DEFIGARD 5000®

Defibrillator and Monitor

User Guide

Art. no.: 0-48-0060 Rev.: a

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The Art of Diagnostics

Sales and Service Information

The SCHILLER sales and service centre network is world-wide. For the address of your local distributor, contact your nearest SCHILLER subsidiary.
In case of difficulty a complete list of all distributors and subsidiaries is provided on our internet site:
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Table of Contents

Art. no.: 0-48-0060 Rev.: a

Art. no.: 0-48-0060 Rev.: a

Art. no.: 0-48-0060 Rev.: a

Art. no.: 0-48-0060 Rev.: a

1 Safety Notes

1.1 Responsibility of the User

- The device must only be used by qualified physicians or other persons (only AED mode) trained in early defibrillation.
- The numerical and graphical results as well as any interpretation suggested by the device must be examined with respect to the patient's overall clinical condition and the quality of the recorded data.
- The indications given by this equipment are not a substitute for regular checking of vital functions.
- Make sure that the user has read and understood the user guide, and especially these safety notes.
- Damaged or missing parts must be replaced immediately.
- It is the owner's responsibility that the valid regulations for safety and prevention of accidents are observed.
- The device must be stored inaccessible to children.
- Properly dispose of the package material and make sure it is out of children's reach.

1.2 Intended Use

- The DEFIGARD® 5000 is a defibrillator used for the treatment of ventricular fibrillation (VF) and ventricular tachycardia (VT). The DG 5000 additionally has a pacemaker function. The monitoring side of the DEFIGARD 5000 gives the most important parameters: ECG, SpO2 and NIBP and allows continuous monitoring of the patient from the beginning to the end of the intervention.
- The device is only intended for single patient use.
- The DEFIGARD® 5000 is intended for hospital use.
- The device can be used for adults and children with the corresponding accessory.
- The defibrillator may only be used if the following symptoms are found:
  - non-responsive
  - no respiration
  - no pulse
- The defibrillator must **not** be used in semiautomatic mode (AED) if the person:
  - is responsive
  - is breathing
  - has pulse
- The DEFIGARD® 5000 is an emergency device that must be ready for use at any time and in any situation. Make sure that the device is always connected to the mains or vehicle power supply.
- Only operate the device in accordance with the specified technical data.
- Do **not** use the device in areas where there is any danger of explosion or in the presence of flammable gases such as anaesthetic agents.

Art. no.: 0-48-0060 Rev.: a

1.3 Organisational Measures

- ▲ Before using the unit, ensure that an introduction regarding the unit functions and the safety precautions has been provided and understood.
- ▲ Always store the user guide handy near the device. Make sure that the user guide is always complete and readable.
- ▲ In addition to this user guide, also legal and other binding regulations for the prevention of accidents and for environment protection must be observed.

1.4 Operational Precautions

- ▲ This user guide, and especially these safety notes, must be read and observed.
- ▲ Danger of electric shock!
  The energy applied to the patient can be conducted through the patient to other persons, who may suffer a lethal electric shock. For this reason:
  - – Do not touch the patient, the electrodes or other conducting objects during a defibrillation
  - – Do not defibrillate the patient in a puddle of water or on other conducting surfaces.
  - – Switch the device off when it is no longer used.
- ▲ To grant the patient's safety, it must be ensured that neither the electrodes, including the neutral electrode, nor the patient, or persons touching the patient, come into contact with conducting objects (e.g. RS-232 interface - see Fig. 3.1 on page 15), even if these are earthed.
- ▲ Changes, including concerning operational behaviour, affecting safety must be immediately reported to the responsible.
- ▲ Only connect original SCHILLER accessories to the device.
- ▲ Before switching on, check if the unit's casing and electrode connection are undamaged.
- ▲ Do not expose the device to great temperature variations over a long period of time. Too great temperature variances can cause condensation water on the unit. If condensing water should occur nevertheless, dry the unit, the defibrillation electrodes and all connections.
- ▲ Special caution must always be taken on intracardiac application of medical equipment. Especially make sure that no conducting parts connected to the isolated patient input (patient, plug, electrodes, sensor) come into contact with other, earthed conductive objects, as this might short-out the patient's isolation and remove the protection of the isolated input.
- ▲ Position the device so that there is no possibility of it falling on the patient or floor.

Art. no.: 0-48-0060 Rev.: a

1.5 Operation with other Devices

- ▲ Use only accessories and other parts recommended or supplied by SCHILLER AG. Use of other than recommended or supplied parts may result in injury, inaccurate information and/or damage to the unit.
- ▲ The patient can be endangered by too high leakage currents (summation of leakage currents) if:
  - – several devices are connected to the patient
  - – other equipment is connected to the DEFIGARD 5000

  For this reason, devices that are not required should be disconnected from the patient, and only equipment approved by SCHILLER may be connected to the DEFIGARD 5000.
- ▲ Accessory equipment connected to the analogue and digital interfaces must be certified according to the respective IEC standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore, all configurations shall comply with the valid version of the system standard IEC/EN 60601-1-1. Everyone who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1-1. If in doubt, consult the technical service department or your local representative.
- ▲ Magnetic and electrical fields of X-ray equipment, tomographs, radio systems, cellular phones etc. can disturb the unit's function. Avoid using such devices and keep a sufficient distance from them.
- ▲ The charging of energy and the release of the defibrillation impulse can disturb other devices. Check these devices before their further use.
- ▲ Sensors and devices that are not defibrillation proof must be disconnected from the patient before a shock is triggered.
- ▲ If the patient has a pacemaker implanted, do not position the electrode directly onto the pacemaker. Check the pacemaker after the defibrillation.
- ▲ The input terminals of the DEFIGARD® 5000 are protected against the influences of high-frequency electrosurgical equipment. Nevertheless, precautions must be observed when high-frequency devices are used at the same time. To reduce the risk of burns in the case of a failure of the neutral HF electrode, a distance of at least 15 cm must always be kept between the defibrillation electrodes and the HF surgical electrodes. If in doubt, disconnect the electrodes and sensors from the unit during use of a HF surgical device.

1.6 Maintenance

- ▲ Danger of electric shock! Do not open the device. No serviceable parts inside. Refer servicing to qualified personnel only.
- ▲ Before cleaning, switch the unit off and remove the battery.
- ▲ Do not use high temperature sterilisation processes (such as autoclaving). Do not use e-beam or gamma radiation sterilisation.
- ▲ Do not use aggressive or abrasive cleaners.
- ▲ Do not, under any circumstances, immerse the device or cable assemblies in liquid.

Art. no.: 0-48-0060 Rev.: a

1.7 General Safety Notes

▲ Operating a device with a defective casing or defective cables constitutes a danger to the patient or user! For this reason:

– Immediately replace a damaged unit, or damaged cables and connections.

1.8 Additional Terms

1.8.1 Implied Authorisation

Possession or purchase of this device does not convey any express or implied license to use the device with replacement parts which would alone, or in combination with this device, fall within the scope of one or more patents relating to this device.

1.8.2 Terms of Warranty

Your SCHILLER DEFIGARD 5000 is warranted against defects in material and manufacture for the duration of one year (as from date of purchase). Excluded from this guarantee is damage caused by an accident or as a result of improper handling. The warranty entitles free replacement of the defective part. Any liability for subsequent damage is excluded. The warranty is void if unauthorised or unqualified persons attempt to make repairs.

In case of a defect, send the apparatus to your dealer or directly to the manufacturer. The manufacturer can only be held responsible for the safety, reliability, and performance of the apparatus if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by him, and
- the DEFIGARD 5000 and approved attached equipment is used in accordance with the manufacturer's instructions.

There are no express or implied warranties which extend beyond the warranties hereinabove set forth. SCHILLER makes no warranty of merchantability or fitness for a particular purpose with respect to the product or parts thereof.

Art. no.: 0-48-0060 Rev.: a

1.9 Display Symbols/Indicators

1.9.1 Symbols Used in this User Guide

The hazard levels are classified in accordance with ANSI Z535.4. The following overview shows the used safety symbols and pictograms used in this manual.

For an imminently hazardous situation which, if not avoided, will result in death or serious injury.

For a potentially hazardous situation which, if not avoided, could result in death or serious injury.

For a potentially hazardous situation which, if not avoided, may result in minor or moderate injury. It may also be used to alert against damage to equipment.

For general safety notes like those in this chapter.

For electrical hazards, warnings or precautionary measures when dealing with electricity.

NOTE For possibly dangerous situations, which could lead to damage to property or system failure or **IMPORTANT** for helpful user information.

Reference to other user guides.

Art. no.: 0-48-0060 Rev.: a

1.9.2 Symbols Used on the Device

BF symbol. The device's signal input is defibrillation protected.

Signal input type CF: High-insulation port, suited for intracardiac application, defibrillation protected.

CE 0459

Notified body for CE certification. (G-MED)

Note: Follow the instructions in the documentation.

SCHILLER potential equalisation.

Symbol for the recognition of electrical and electronic equipment

The device must be disposed of in a municipally approved collection point or recycling centre when it is no longer required.

Improper disposal harms the environment and human health due to dangerous substances contained in the equipment.

1.9.3 Symbols Used on the Battery

The unit/component can be recycled.

Battery may not be disposed of with domestic refuse.

Do not burn, saw up or crash the battery.

Rechargeable battery

Do not short the battery

Storage temperature for the battery:
Unlimited: 0...+40 °C

Expiration date

Art. no.: 0-48-0060 Rev.: a

1.9.4 Symbols Used on the Electrode Package


Open the electrode package


Peel off the protective foil


Disposable item; do not reuse


Do not bend packing

Storage temperature for the electrodes


Expiration date

Art. no.: 0-48-0060 Rev.: a

2 Components and Operation

The **DEFIGARD® 5000** is a lightweight mains and battery powered defibrillator featuring an ECG monitor, a recorder, SpO2 measurement, NIBD and a transcutaneous pacemaker. It is designed for clinical use. Defibrillation is possible in non-synchronised or synchronised mode.

Moreover, the device can be switched to automatic defibrillation (AED operation) by pressing a single key.

Biocompatibility

The parts of the product described in this user guide, including all accessories, that come in contact with the patient during the intended use, fulfil the biocompatibility requirements of the applicable standards. If you have questions in this matter, please contact SCHILLER.

2.1 Design

Power Supply

The DEFIGARD® 5000 is either powered by the mains or an integrated rechargeable battery. The capacity of one battery is sufficient for:

- 190 shocks with max. energy or
- 2 hours monitoring

Defibrillator

The **DEFIGARD® 5000** is a defibrillator featuring biphasic pulsed defibrillation impulse – ***Multipulse Biowave®***. The defibrillation is done using paddles, disposable adhesive electrodes (pads) or spoons (internal defibrillation), which also measure the ECG signal for the analysis. Adhesive electrodes for children and adults are available. The device recognises the connected electrodes and selects the defibrillation energy levels accordingly. In the AED mode, the user will be given visual and audible instructions (display/loudspeaker).

External cardiac pacemaker

The **DEFIGARD® 5000** pacemaker function can at any time be activated via the adhesive electrodes. In the menu, the fix, demand and overdrive operational modes can be selected.

Monitoring

The **DEFIGARD® 5000** monitoring function gives all important parameters – ECG, SpO2 and NIBP. The parameters are indicated in figures and as waveforms on the large LCD display.

Data storage

The ECG and trends are saved in the device. Three ECG curves can be printed on the integrated printer:

Data transmission

- Easy transmission of a 12 lead ECG by GSM or standard modem connected to the back of the device
- USB connector for use with for example, a memory stick to copy the stored data
- Ethernet connector for software updates

Art. no.: 0-48-0060 Rev.: a

2.1.1 Available Options

- Additional battery, type Li/ion; 10.8 V, 4.3 A

2.1.2 Overview of the Configurable Settings

The following settings can be configured by the SCHILLER after-sales service:

- Voice volume
- Energy levels of the first, second and third shocks, individually for adults and children

Art. no.: 0-48-0060 Rev.: a

2.2 Operating Elements

2.2.1 Front Side

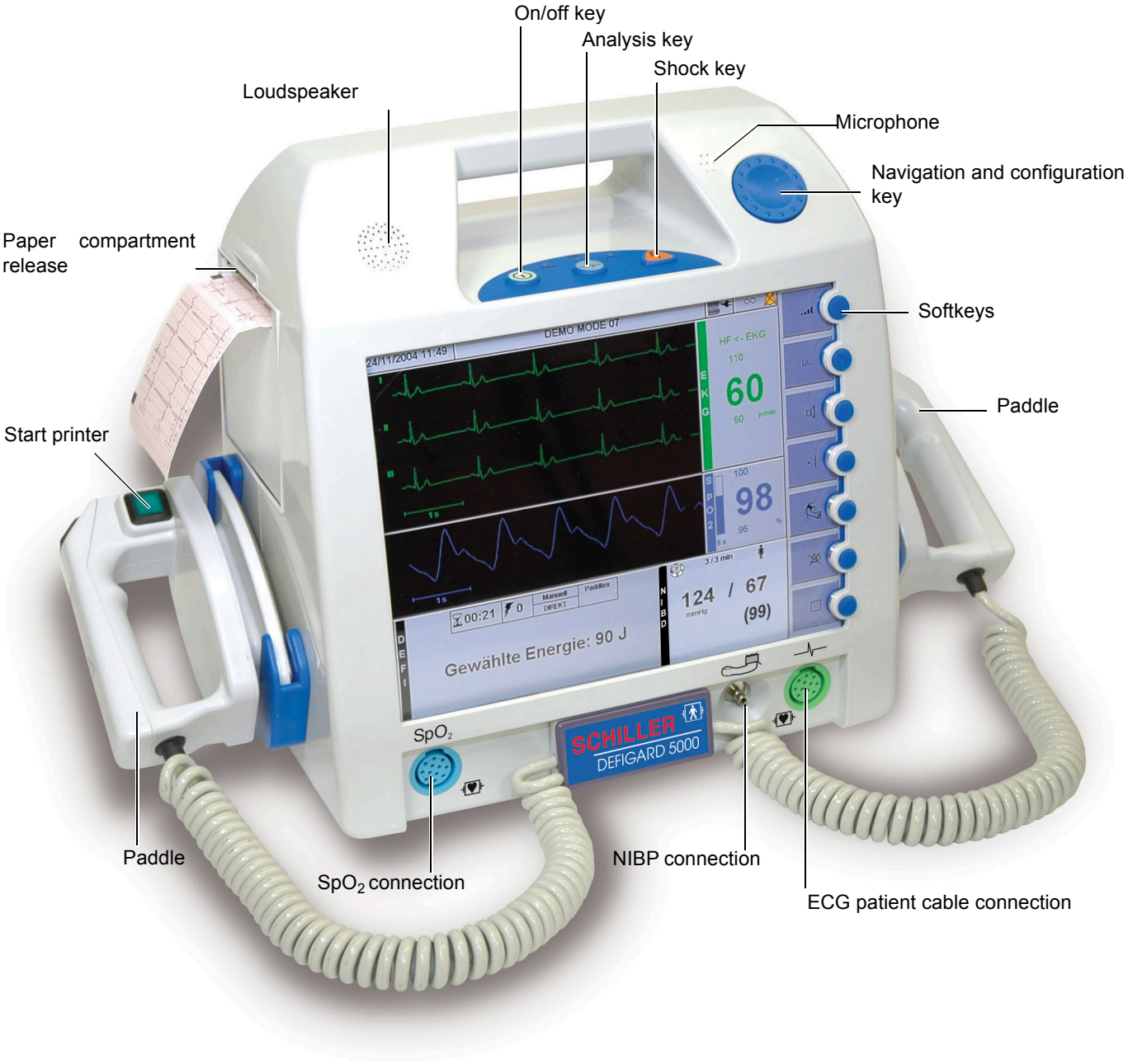


Fig. 2.1 Control elements of the DG5000's front

Art. no.: 0-48-0060 Rev.: a

2.2.2 Back Panel

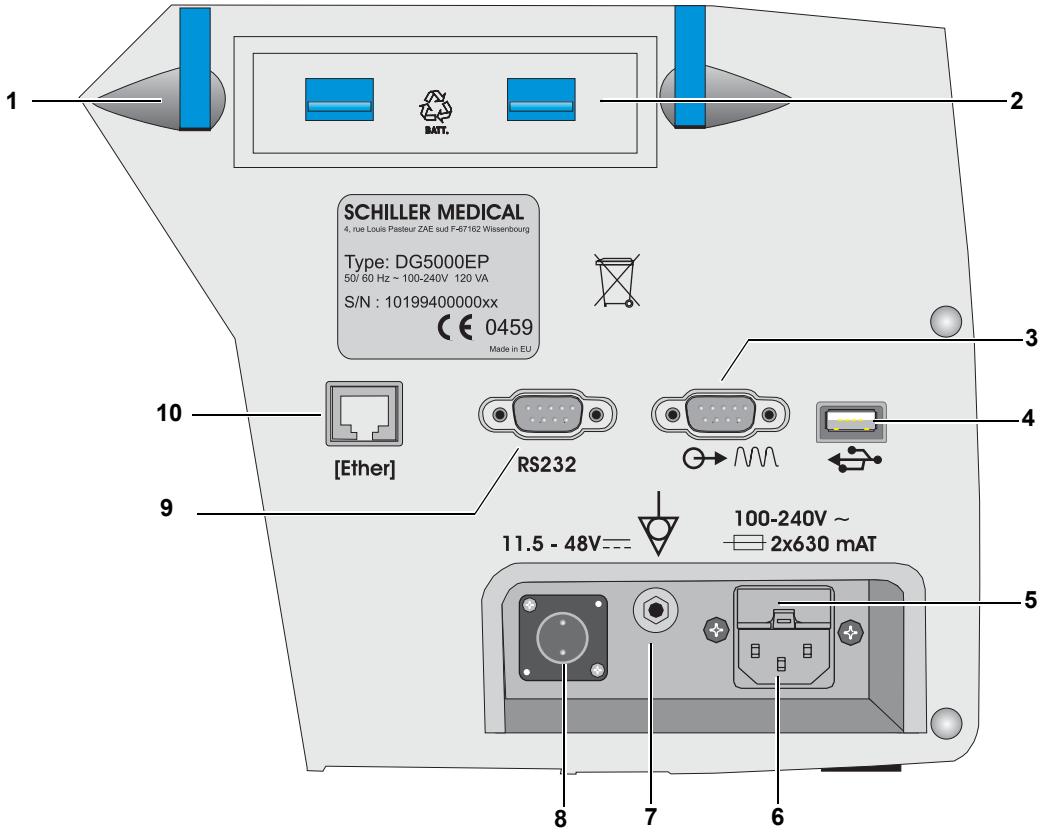


Fig. 2.2 Control elements at the DG5000's back

(1) Swing-out fastening bows
(2) Additional battery (option)
(3) Signal output (QRS trigger, 1-channel ECG, remote alarm)
(4) USB connector for use with a memory stick to copy the stored data
(5) Fuses
(6) Mains connector
(7) Potential equalisation
(8) Connection for an external constant voltage source 11.5...48 VDC (e.g ambulance)
(9) RS-232 interface for GSM or standard modem
(10) Ethernet connector for software updates

⚠ CAUTION

▲ The plug-in connections are only designed for the connection of equipment or accessories supplied by SCHILLER.

Art. no.: 0-48-0060 Rev.: a

2.2.3 Paddle Operation Elements

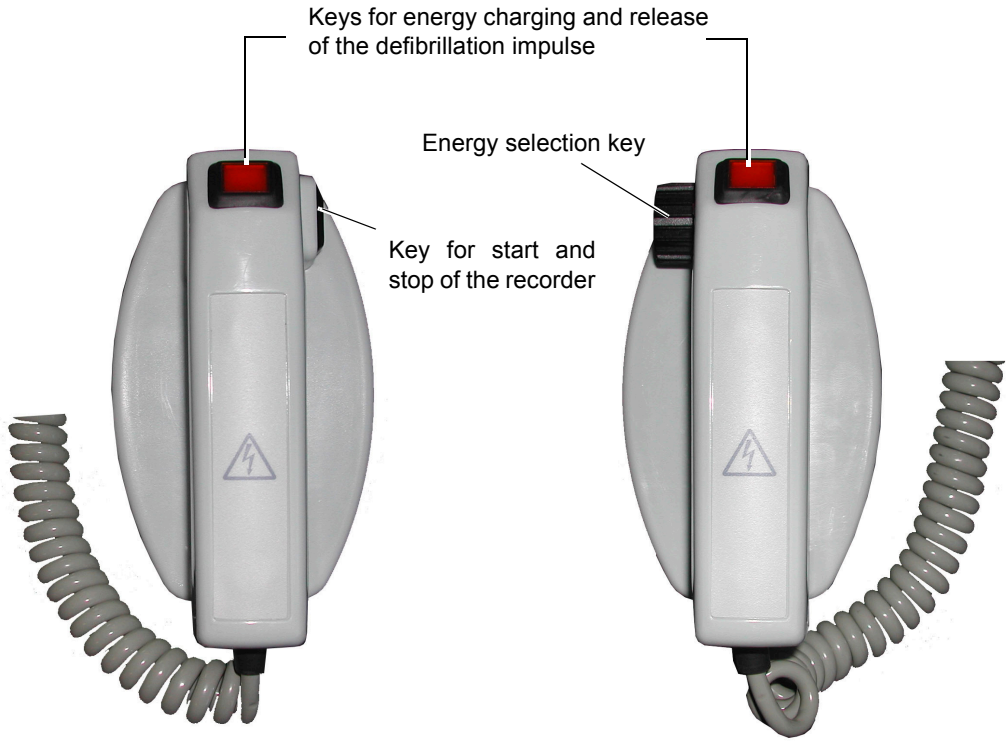


Fig. 2.3 Paddles operation elements

2.2.4 LEDs

The LEDs give the following information:

(1) Operation with external constant voltage source
(2) Flashes while the battery is being recharged
(3) Unit connected to the mains

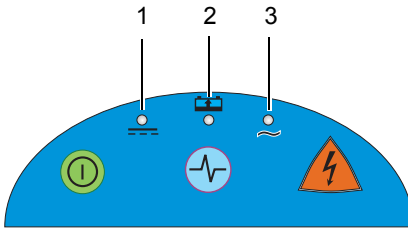


Fig. 2.4 Keys and LEDs

Art. no.: 0-48-0060 Rev.: a

2.2.5 Display

The display can vary according to the settings and used options. E.g. when 4 leads are selected, the SpO_2 waveform field is not displayed and only the measured values to the right are visible.

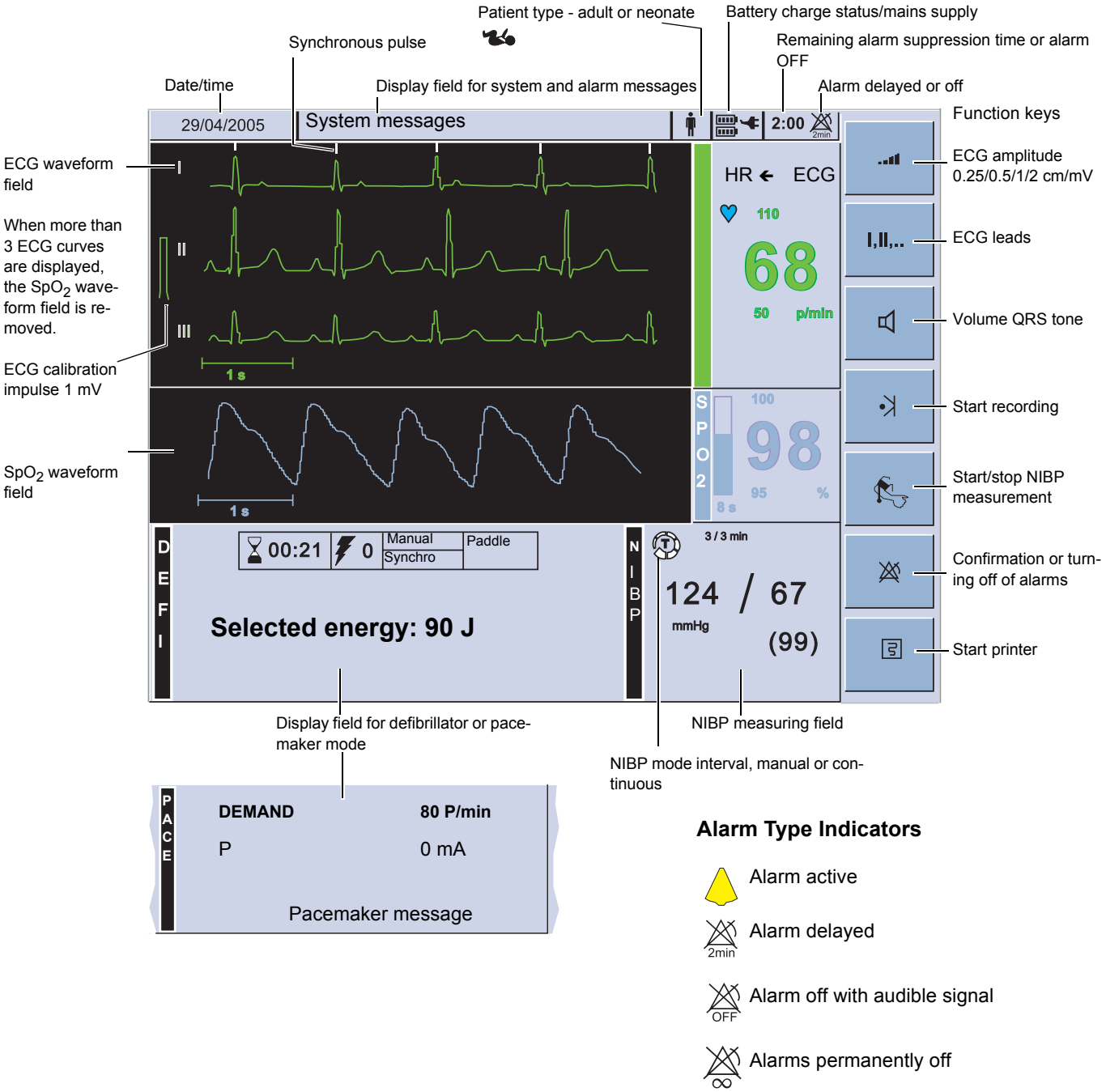


Fig. 2.5 Display elements of the DEFIGARD 5000

Art. no.: 0-48-0060 Rev.: a

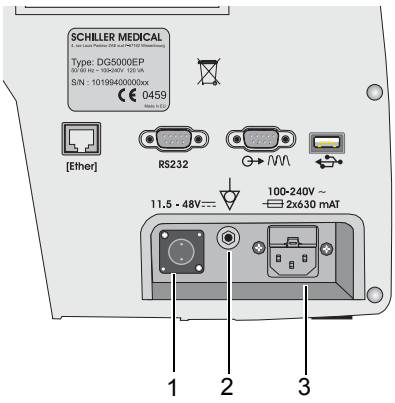
3 Start-up and Initial Preparation

DANGER

- ▲ Danger of electrical shock. Do not operate the unit if the earth connection is suspect or if the mains lead is damaged or suspected of being damaged.
- ▲ Please read the safety notes in section 1 before initial operation.
- ▲ Danger of explosion! The device is not designed for use in areas where an explosion hazard may occur. Also, it is not permitted to operate the defibrillator in an oxygen-enriched environment or in the presence of flammable substances (gas) or anesthetics. Oxygenation in the vicinity of the defibrillation electrodes must be strictly avoided.
- ▲ Danger of electrical shock. The DEFIGARD® 5000 is a high-voltage therapy device. Improper use of the device can endanger life. Always follow the instructions given in this user guide.
- ▲ The user must make sure that there are no conductive connections between the patient and other persons during ECG analysis and defibrillation.
- ▲ Avoid defibrillation in very moist or wet surroundings.

3.1 Mains and Battery Operation

3.1.1 Connecting the Unit to the Mains and Switching it on



1. Connect the mains cable to the rear of the unit (3) and to the mains (100 V – 240 V). The mains voltage LED is lit and the battery charge LED flashes.
2. If necessary, connect the potential equalisation cable (2) to the central potential equalisation socket.
3. Press the **on/off** button.
4. Check the settings according to section Default and User-Defined Thresholds on page 63.
5. Connect the other needed cables.

Fig. 3.1 Connections

To prevent leakage current, the device must be connected to the room's central potential equalisation via the potential equalisation socket.

A potential equalisation cable (article no. U50030) can be obtained from SCHILLER.

Art. no.: 0-48-0060 Rev.: a

3.1.2 Battery Operation

Charging the Battery

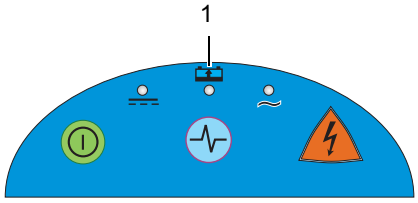


Fig. 3.2 LED battery operation

Important

The internal battery is automatically recharged when the device is connected to the mains (or an external constant voltage source). The battery requires approx. 1 hour to be 80% recharged.

The recharging of the battery is indicated by the LED below the battery symbol.

– LED (1) flashes while the battery is being recharged.

Fig. 3.3 Battery low indication

Battery Low Indication

When the battery is low, a flashing battery symbol is displayed at the top of the screen. The arrows show which of the batteries (upper ↑ or lower ↓) is low.

3.1.3 Operation with External Constant Voltage Source

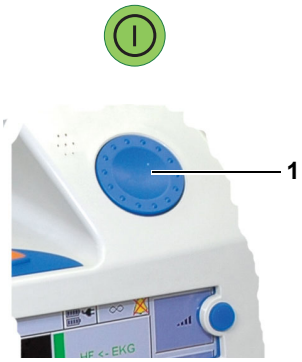
The DEFIGARD® 5000 can be connected to an external 11.5...48 V constant voltage source (e.g. vehicle battery) by a technician (see 1, Fig. 3.1). For this, the following must be observed:

- The negative terminal of the ambulance power supply must be connected to chassis.
- The connecting leads must have a minimum diameter of 1.5 mm^2. All terminals and plugs must be designed to withstand high currents.
- The positive lead must be protected with a 10 A fuse.

  – The LED ⎓ lights up when the device is powered from the external DC source.

Art. no.: 0-48-0060 Rev.: a

3.2 Switching off and Disconnecting from Mains



1. Press the **on/off** button.
2. Select **Yes** using the configuration key (1).
3. Confirm the selection by pressing the configuration key.
4. Remove the mains cable Fig. 3.1 to disconnect the device from the mains if you do not want to recharge the battery.

3.2.1 Internal Safety Discharge

The **DEFIGARD® 5000** has an internal safety discharge circuit for internal discharge of the stored energy. The defibrillator displays the message "Internal discharge" during the safety discharge. The energy is internally discharged when

- the shock is not delivered within 20 s of charging
- a lead failure occurs
- a lower energy value is selected while the defibrillator is charging
- a shock is delivered into open air
- the battery voltage is insufficient
- the device is defective
- the device is turned off

Furthermore the residual energy stored in the defibrillator 100 ms after shock release is always discharged internally.

3.2.2 Mains Supply Interruption

If the mains supply is interrupted, the device automatically switches over to battery operation. The user settings are maintained. These settings can be saved.

3.2.3 Ensuring Operational Readiness

- Do not expose the device to direct sunlight, or extremely high or low temperatures. The ambient temperature should be in the range of 0 °C...50 °C. Lower or higher ambient temperatures will have a negative impact on the battery's life.

To ensure its readiness for use, the device runs a self-test to check the unit and the battery. The self-test is run:

- when the device is turned on
- automatically (the self-test intervals can be defined by the user in the settings).

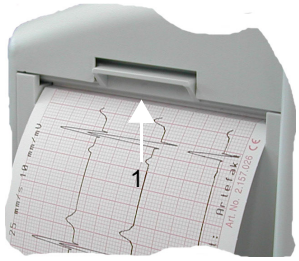
If the device detects an error during the self-test, an error message is displayed.

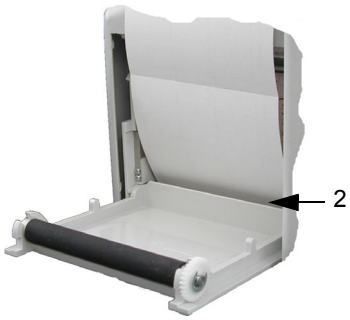
Art. no.: 0-48-0060 Rev.: a

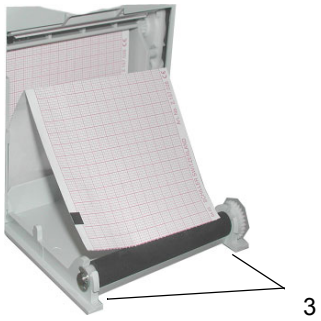
3.3 Inserting Printing Paper

Important

The device is delivered without printing paper installed. Only use original SCHILLER printing paper. The thermo-paper is sensitive to heat, humidity and chemical vapours. Store the paper in a cool and dry area.







1. Press the locking catch (**1**) upwards. The printer door opens downward.
2. Insert paper and pull it up. Be sure that the paper lies behind the cover (**2**).
3. Close the cover. Be sure that the paper lies exactly between the rails (**3**).

Art. no.: 0-48-0060 Rev.: a

3.4 Operation

The menus can be accessed in two ways:

- Direct access by pressing the navigation button
- By turning the navigation button to select the desired box and then pressing the button to enter the menu

3.4.1 Direct Menu Access

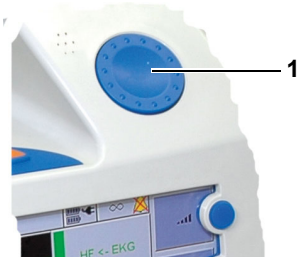


Fig. 3.4 Turn and press the navigation button

1. Press the navigation button (**1**). When the button is pressed twice, the main menu is directly opened and step 2 is dropped.
2. The main menu is opened by pressing the **Menu** softkey (**2**). The main menu is displayed. (See Fig. 3.5)
3. To select, display or modify a menu, turn and press the button.
4. To exit a menu, press **Enter** ↵ .

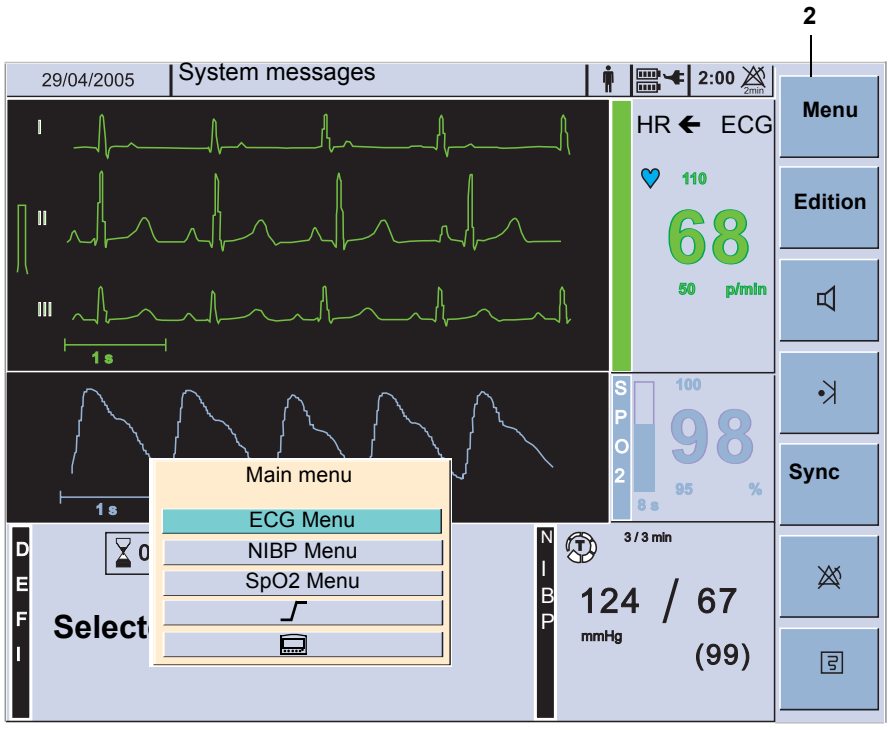


Fig. 3.5 Display with main menu

The threshold values can be changed either via the different menus or directly in the threshold menu ⎍ .

The time, volume and printer configuration can be set in the unit settings menu ▭ .

Art. no.: 0-48-0060 Rev.: a

3.4.2 Accessing Menus and Function Keys via Display Fields

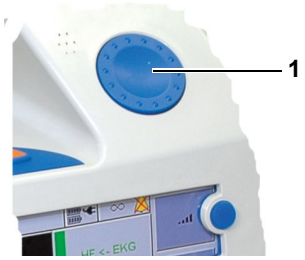


Fig. 3.6 Turn and press the navigation button

1. Select the desired display field using the navigation button (**1**). The selected display field (**2**) is shown with a different background colour and flashes. The softkeys (**3**) change their functions depending on the selected field.
2. The selected menu (**4**) is displayed by pressing the navigation button.
3. To leave the menu, press the navigation button twice.

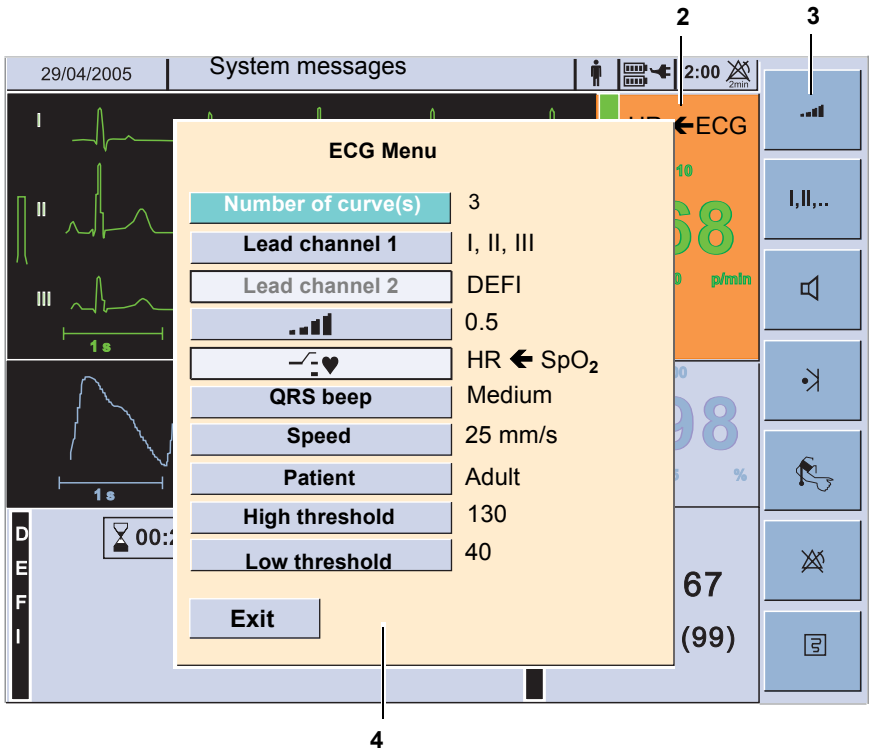


Fig. 3.7 Menu access via display field

Art. no.: 0-48-0060 Rev.: a

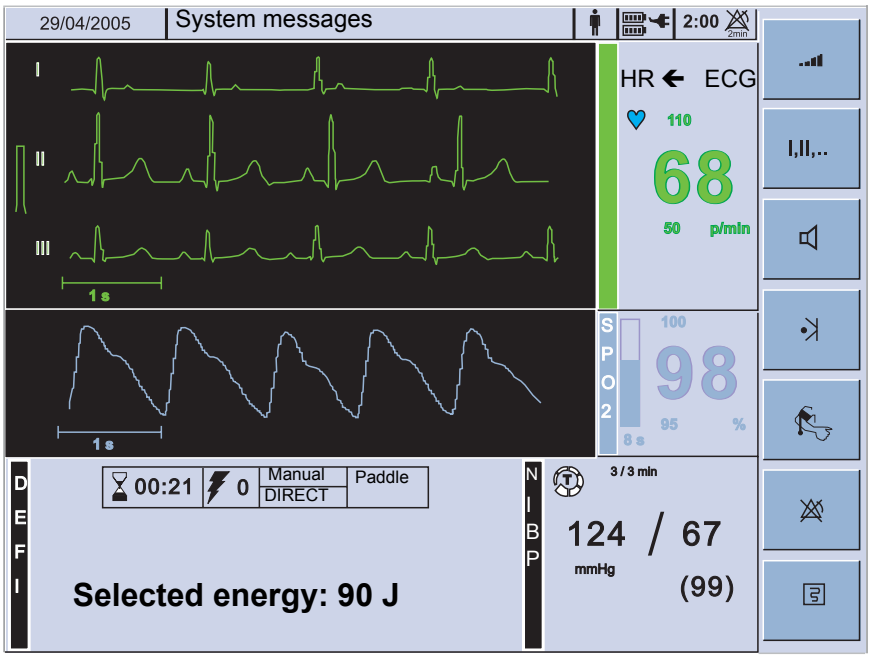
4 Monitoring

The operation and menu access are detailed on page 22.

4.1 Softkeys, Waveforms and Measurement Fields

The waveform and measurement fields are automatically displayed when the device is switched on, whereas the ECG and SpO_2 are only displayed when the corresponding patient cable or sensor is connected.

The device can basically be operated via the softkeys on the right of the display. The functions of these keys vary according to the selected waveform field.



Settings

The settings that are defined via the softkeys or menus remain saved when the unit is switched off and will automatically be active when it is switched on again.

Art. no.: 0-48-0060 Rev.: a

4.2 Alarm Messages

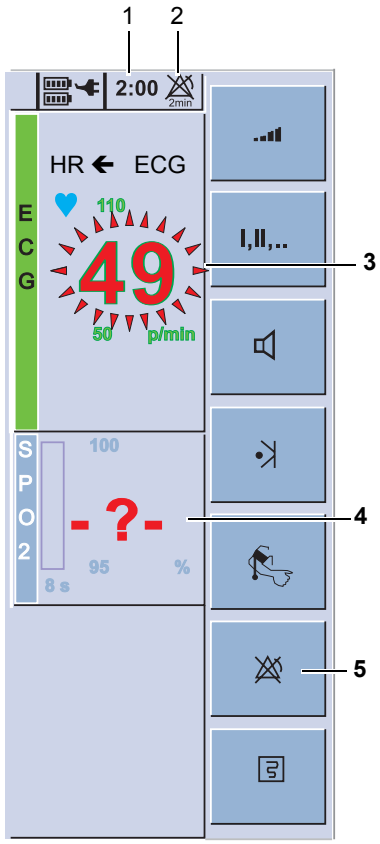


Fig. 4.1 Alarm indicators

Physiological Alarms

When a measurement reading exceeds an alarm limit, an alarm is triggered after 3 seconds and

- the measurement value field **3** flashes red
- an interrupted alarm sounds (4 beeps/s)
- An error message is displayed on the top of the alarm field

Technical Alarms

When a technical error occurs:

- An error message is displayed on the top of the alarm field
- an interrupted alarm sounds (2 beeps/s)
- A question mark is displayed instead of the measurement reading **(4)**
- if a threshold value is exceeded, **-?-** is displayed.

Contrary to alarms due to violation of alarm limits, which must be acknowledged by pressing a key (**5**) according to the settings, this alarm clears automatically as soon as its cause is no longer present.

Suppressing an Alarm Sound

Suppress the alarm by pressing the button **(5)**:

- If you press the button briefly, the alarm remains suppressed for 2 min and the symbol **(1)** is replaced by the remaining time in minutes.
- If you keep the button pressed for approx. 3 s, it remains shut off until it is reactivated by the same button. The ∞ symbol is displayed instead of the time (**1**) and a beep sounds every 2 min.

The measurement reading will flash red until it returns to the normal range.

Activating the Alarm Sound

To reactivate the alarm, press the button **(5)** again.

In some countries it is not permitted to disable audio alarms permanently. Therefore, this function can be configured. (See page 68, section 10.3.1.)

Alarm Symbols (2)

Alarm active

2min

Alarms suppressed for 2 minutes. This symbol is displayed when the alarm suppression key (**5**) is pressed.

OFF

Threshold value alarms off (except min. HR and min. pulse SpO_2). This symbol is displayed when the alarm suppression key (**5**) is pressed, but only if the alarm settings are off. Technical alarms will still be issued.

∞

Alarms permanently off. This symbol is displayed when the alarm suppression key (**5**) is pressed for 3 s, but only if the alarm settings in the device settings menu are permanently off.
(See page 68, section 10.3.1.)

Art. no.: 0-48-0060 Rev.: a

4.3 ECG and Heart Rate Monitoring

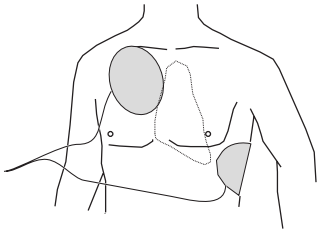
⚠WARNING

- ▲ False diagnosis . Only use silver/silver-chloride electrodes if the patient may have to be defibrillated while the ECG is being displayed. Other electrodes may create high polarisation voltages and the ECG trace on the monitor and on the recording may simulate cardiac arrest.
- ▲ Danger of destroying the device during defibrillation! The device is only type CF protected if the original SCHILLER patient cables are used.
- ▲ Patients with a pacemaker must be observed continuously because the heart rate from the pacemaker might still be registered in case of a cardiac arrest or some arrhythimas.

Important

The guidelines for patient electrode placement are provided as an overview only. They are not a substitute for medical expertise.

4.3.1 Quick Diagnosis of the ECG Using Defibrillation Electrodes

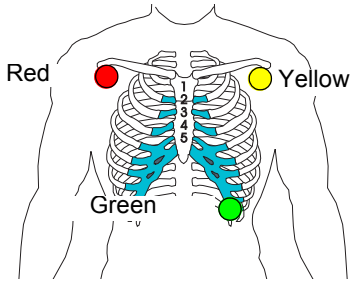


For a quick diagnosis, the ECG signal can be recorded from the patient's thorax using the defibrillation electrodes. In all other situations, we recommend acquiring the ECG via ECG electrodes and the patient cable.

If no patient cable is connected, the ECG is automatically sensed with the defibrillation electrodes (lead designation "DEFI").

Fig. 4.2 Defibrillation electrodes

4.3.2 Connecting a 3-Lead ECG Patient Cable



ECGs acquired with a 3 or 4-lead patient cable are automatically displayed in channels 1 and 2, if no other parameter is activated.

When a patient cable is connected and the adapter module for defibrillation electrodes is inserted, you can select the signal source in the ECG menu.

Fig. 4.3 3-lead cable

Art. no.: 0-48-0060 Rev.: a

4.3.3 Connecting a 4- or 10-Lead ECG Patient Cable

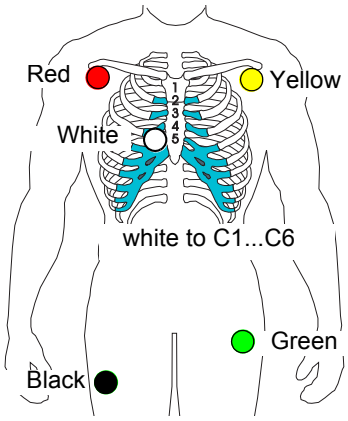


Fig. 4.4 4- and 10-lead cable

ECGs acquired with the 10-lead cable are displayed in all three channels, if no other parameter is activated.

When a patient cable is connected and the adapter for defibrillation electrodes is inserted, you can select the signal source in the ECG menu.

Art. no.: 0-48-0060 Rev.: a

4.3.4 Starting ECG Monitoring

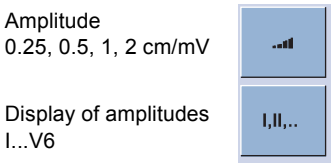


Fig. 4.5 ECG softkeys

1. Apply the electrodes as shown in Fig. 4.3 or Fig. 4.4.
2. Connect the patient cable to the ECG signal input.
3. Define the ECG settings directly via the softkeys.
4. Open the ECG menu and check the settings.

4.3.5 Monitoring a Pacemaker Patient

⚠ DANGER

▲ **Erroneous HR readout**. In the monitoring of pacemaker patients, we cannot exclude the possibility of pacer pulses being counted as QRS complexes. Therefore, pacemaker patients should always be watched closely. We recommend monitoring pacemaker patients by means of the plethysmogram (HR source = SpO_2 in the ECG or SpO_2 menu).

When monitoring the heart rate of pacemaker patients, it is important that the device will only count the QRS complexes and reject the pacer pulses.

The DEFIGARD® 5000 has an electronic pacer pulse suppression algorithm which rejects the pacer pulses so they are not counted as QRS complexes. Depending on the pacemaker model used and on the position of the electrodes, the compensation pulse following every pacer pulse may be considered as a QRS complex. In this situation and when the pacer pulse is ineffective, the displayed heart rate may lead to a misinterpretation, and the device will not give alarm in the case of bradycardia or asystole. It depends on the pacer pulse parameters whether or not the compensation pulse is counted as a QRS complex.

For pacemaker patients, the ECG signal amplitude should be greater than 1 mV.

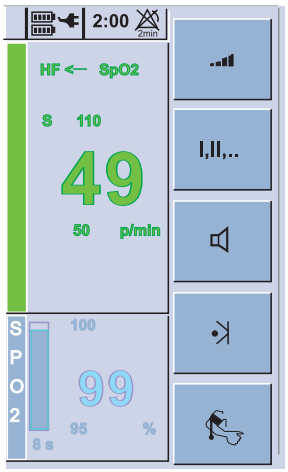


Fig. 4.6 Indication HR source SpO_2

If the source of the heart rate is SpO_2, this is indicated by the HR <- SpO_2 symbol and a flashing S.

Art. no.: 0-48-0060 Rev.: a

4.3.6 ECG Menu

Menu	Parameter	Description	Value
ECG	[a]Number of curve(s)	Number of the curves displayed. When the number is 6, SpO_2 is not displayed.	0 / 1 / 2 / **3** / 6 /12
	Lead channel 1	Preselection of the standard waveform groups that should be displayed.	Defi/**I, II, III**/aVR, aVL, AVF/V1,V2,V3/V4, V5, V6
	Lead channel 2	Preselection of the standard waveform groups that should be displayed.	[b]Defi/**I, II, III**/aVR, aVL, AVF/V1, V2, V3/V4, V5, V6
		ECG amplitude setting.	0.25 / 0.5 / 1 / 2 cm/mV
		[c]Source based on which the heart rate should be determined.	**HR** ← **ECG**/HR ← SpO2
	QRS sound	Volume of the systolic sound	Off/Low/**Medium**/High
	Speed	Speed of the ECG curve display	**25**/50 mm/s
	Patient	Selection of patient type	**Adult**/Neonate
	[d]High threshold	High heart rate threshold	**140**...300/Off
	[c]Low threshold	Lower heart rate threshold	Off/**60** (range 30...125)

a. The number of displayed ECG curves and selectable leads is determined by the type of the patient cable connected.
b. The "Defi" option is only available when a patient cable and an adapter module with defibrillation electrodes are connected.
c. When the patient has a cardiac pacemaker, the HR source must be set to SpO_2 (see page 28).
d. The threshold values are only displayed after the user's threshold values have been opened once in the threshold values menu. (See page 63, section 9.)

4.3.7 ECG Error Messages

Alarm	Cause	Remedy
CONNECT THE ELECTRODES!	• Electrodes not attached to the patient; come off; bad contact	→ Check the contact between the electrodes and the patient's body
	• Electrodes defective; line break	→ Check the ECG cable and electrodes
	• Device defective	→ Have the device repaired
FIBRILLATION	• Ventricular fibrillation or tachycardia with a rate exceeding 180 p/min	→ Physiological alarm!

Art. no.: 0-48-0060 Rev.: a

4.4 SPO_2 Monitoring

- The pulsoximeter enables the continuous non-invasive monitoring of the functional oxygen saturation of the arterial haemoglobin and the pulse rate. When the signal is received from the patient sensor, this signal is used to calculate the patient's functional oxygen saturation and pulse rate.
- The display shows the continuous progress of the numeric SpO2, pulse rate, plethysmographic waveform and signal quality values.
- The displayed plethysmographic curve is not proportional to the pulse volume.
- The update period of the measurement readings on the display is 0.2 seconds.
- According to the relevant standards, the temporary alarm suppression must be set to a maximum of 2 minutes.

⚠WARNING

- ▲ Only use sensors listed in the order information for SpO2 measurement with the DEFIGARD® 5000. Other oxygen transducers (sensors) may lead to improper performance.
- ▲ The information in this user guide does not overrule the instructions given in the user guide of the sensor, which must also be observed.
- ▲ Never use a pulsoximeter during MR imaging. Induced current could potentially cause burns, and the pulsoximetry may affect the image and the accuracy of the measurements.
- ▲ Before using the sensor, carefully read the sensor directions for use.
- ▲ Tissue damage can be caused by incorrect application or use of a sensor. Inspect the sensor site as described in the sensor directions for use to ensure skin integrity and correct positioning and adhesion of the sensor.
- ▲ Do not use damaged patient cables, damaged sensors or a sensor with exposed optical components.
- ▲ Substances causing disturbances: Carboxyhaemoglobin can lead to falsely high measurement readings. The degree of the deviation approximately corresponds to the quantity of carboxyhaemoglobin. Colours or substances containing colours that influence the natural blood pigments can also lead to incorrect measurement readings.
- ▲ Exposure to excessive illumination, such as surgical lamps (especially those with xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight, can affect the performance of an SpO2 sensor. To prevent exposure to excessive illumination, ensure that the sensor is correctly applied and that it is covered with an opaque material, if required. If these measures are neglected, excessive illumination can lead to incorrect measurements.
- ▲ Change the position of the sensor at least every 4 hours, and every 2 hours if the perfusion is low.

4.4.1 Starting SpO_2 Monitoring and Test

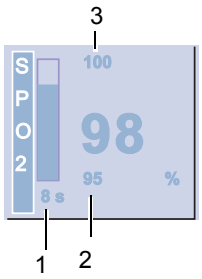


Fig. 4.7 SpO_2 measurement field

1. Apply the SpO_2 sensor to the patient. Insert the patient's forefinger into the probe as far as it will go, and make sure that the finger tip covers all of the probe window. This is to prevent that extraneous light reaches the photodetector.
2. Activate the module by connecting the SpO_2 sensor to the device.
3. Set the lower SpO_2 alarm limit to 99%.
4. When the measured value exceeds the alarm limit, an alarm is issued.
5. Reset the alarm limit to its original value.

Art. no.: 0-48-0060 Rev.: a

4.4.2 SpO_2 Menu

Menu	Parameter	Description	Value
SpO_2	SpO_2 curve	Display of the SpO_2 curve	Yes/no
(**1**)	Average	Definition of the integration time for the calculation of the displayed average value	**8**/16 seconds
		[a]Source based on which the heart rate should be determined	**HR** ← **ECG**/HR ← SpO2
	Speed	Speed of the SpO_2 curve display	**25**/50 mm/s
	Patient	Selection of patient type	**Adult**/Neonate
	High pulse threshold	High pulse alarm limit	(**130**...250)/Off
	Low pulse threshold	Low pulse alarm limit	Off/**50** (range 30...125)
(**3**)	[b]High SpO_2 threshold	High oxygen alarm limit	**100**/Off (range 55...250)
(**2**)	[b]Low SpO_2 threshold	Low oxygen alarm limit	Off/**85** (range 50...99)

a. When the patient has a cardiac pacemaker, the HR source must be set to SpO_2 (see page 28).
b. The threshold values are only displayed after the user's threshold values have been opened once in the threshold values menu. (See page 63, section 9.)

4.4.3 SpO_2 Error Messages

Alarm	Cause	Remedy
Low perfusion	• Weak pulse • Bad sensor positioning	➜ Check/reapply the sensor
TOO MUCH LIGHT!	• Sensor is disturbed by ambient light	➜ Reduce ambient light
CAPTOR PROBLEM!	• Sensor failed	➜ Replace the sensor
ARTEFACTS!	• Measurement disturbed by external influences	➜ Patient must not move
SENSOR OFF PATIENT!	• Sensor not connected to the patient or lose	➜ Check the contact between the sensor and the patient
SEARCH PULSE!	• Device is searching for the pulse	➜ Make sure that the sensor is well connected to the patient
CAPTOR PROBLEM!	• Wrong or defective sensor	➜ Replace the sensor
NO CAPTOR!	• SpO_2 sensor failed or disconnected	➜ Replace the sensor

Art. no.: 0-48-0060 Rev.: a

4.5 NIBP Monitoring

The non invasive blood pressure is measured by the oscillometric method. The criteria for this method are the pressure pulsations superimposed, with every systole, on the air pressure in the cuff, rather than the associated sounds (there is no microphone in the cuff).

The module performs single measurements and automatic measurements at selectable intervals.

During blood pressure measurements the cuff must be on a level with the heart. If this is not ensured, the hydrostatic pressure of the liquid column in the blood vessels will lead to incorrect results. When the patient is sitting, standing or supine during measurements, the cuff is automatically at the correct level.

The blood pressure can be measured in mmHg or in kPa.

WARNING

- ▲ To prevent extensive pressure on the extremity, it is very important to choose the correct cuff size and to check the setting in the panel System/Patient (Adult, Pediatric, Neonatal).
- ▲ In case of long-term monitoring or automatic operation, the connected body areas of the patient and the extremity to which the cuff is attached must be checked regularly for signs of ischaemia, purpura and/or neuropathy.
- ▲ The cuff must not be attached to a limb that is already used for interventions such as infusions.
- ▲ To prevent incorrect measurement results, make sure that the tube is not compressed.

To prevent erroneous SpO_2 measurements, the blood pressure cuff should not be positioned on the limb on which the SpO_2 is measured.

Art. no.: 0-48-0060 Rev.: a

4.5.1 Starting NIBP Monitoring

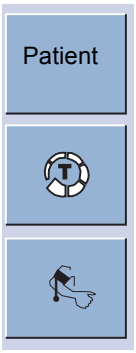


Fig. 4.8 NIBP softkey

1. Note the cuff size for the respective patient type.
2. The cuff is attached to the left or right upper arm. About 4 cm above the elbow (on children and infants a little closer).
3. Connect the cuff tubing to the connection sleeve and make sure it properly locks into place.
4. Define the NIBP settings directly via the softkeys.
   – Patient type – adult or neonate. (Indicated at the top right.)
   – Setting of the cycle time or manual measurement
   – Start of the NIBP measurement
5. Open the NIBP menu and check the settings.
6. Start the NIBP measurement by pressing the softkey.
7. To disconnect the cuff tube, press the milled shell of the connecting sleeve backwards.

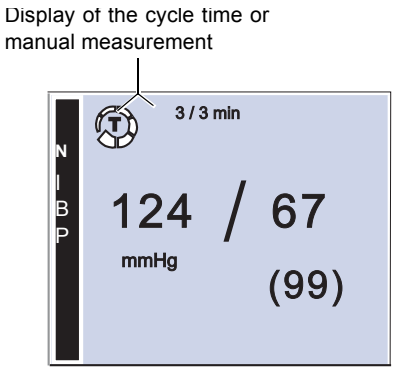


Fig. 4.9 NIBP measuring field

The following settings are available for the cycle time:

3/3 min	Time remaining until the next measurement/cycle time
Manual	The measurement is manually initiated by pressing the softkey.
Continuous	A measurement is taken every 10 seconds for a certain period of time. The period can be set in the range of 5...15 min.

The NIBP measurement must be initiated via the NIBP start softkey, regardless of this setting.

When the measurement is started, the measurement readings are replaced by the cuff pressure and the number of attempts.

Art. no.: 0-48-0060 Rev.: a

4.5.2 NIBP Menu

Menu	Parameter	Description	Value
NIBP		Cycle time setting	Manual, Continuous or cycle of 1/2/3/ 5/10/15/20/30/40/90 minutes
	Patient	Selection of patient type	**Adult**/Neonate
	Unit	Unit setting of mmHg or kPa	**mmHg / kPa**
	Calibration	Calibration of the NIBP module	This function requires a password from the service department
	[a]High SYS threshold	High systolic alarm limit	**180** (70...250)
	[a]Low SYS threshold	Low systolic alarm limit	**70** (Off/50...225)
	[a]High MAP threshold	High alarm limit for average pressure	**160** (25...250)
	[a]Low MAP threshold	Low average limit for average pressure	**50** (Off/20...245)
	[a]High DIA threshold	High diastolic alarm limit	**110** (15...200)
	[a]Low DIA threshold	Low diastolic alarm limit	**40** (Off/10...195)

a. The threshold values are only displayed after the threshold menu has been opened once. (See section 9, page 63.)

4.5.3 NIBP Error Messages

Alarm	Cause	Remedy
NIBP error	• NIBP module failed	→ Replace the device
Zero pressure	• No pressure can be measured • Device defective	→ Check cuff and connection → Replace the device
Low pressure	• Pressure below limits	→ Check cuff and connection
Insufficient pressure	• Pressure in the cuff remains too low	→ Check cuff and connection for leaks
Bad cuff	• Pressure too high because - Too small cuff applied - Tube buckled	→ Check cuff and connection
Measure too long	• Measurement time exceeded with no results	→ Check cuff and connection → Make sure that the cuff is well applied
ARTEFACTS!	• Measurement disturbed by external influences	→ The patient must not move during measurement
Low pulse	• Pulse amplitude too low	→ Apply cuff correctly
Measure too old	• Last measurement more than 15 minutes ago	→ None (just for information); if required, start a new measurement
Pump >20 s	• Pumping running time exceeded	→ Check cuff and connection for leaks

Art. no.: 0-48-0060 Rev.: a

4.6 Trend Display

The trends present the vital signs collected over a period of time in an easy to read format. You can choose between the graphic format (trend curve) and the tabular format.

4.6.1 Displaying Trends

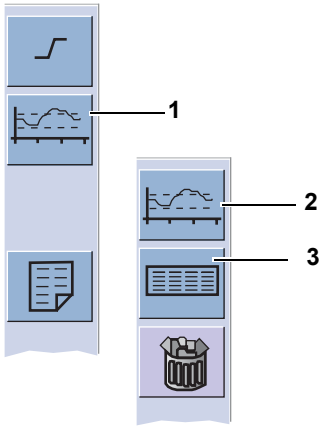


Fig. 4.10 Accessing the trend displays

1. Press the navigation button.
2. Press the **Edition** softkey.
3. Press the trend key (**1**).
4. Press trend curve (**2**) or trend table (**3**) key.
5. Configure the desired curves or table values in the respective menu and confirm your settings with OK. The table or curve is displayed.

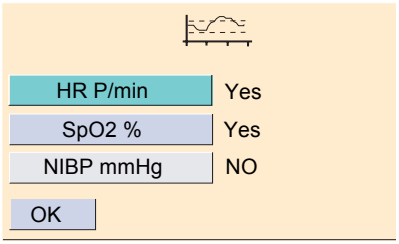


Fig. 4.11 Curve settings

Curve Settings

Up to two curves can be displayed.

1. Select the curve combination with Yes.
2. Confirm your settings with OK. The trend display is opened.

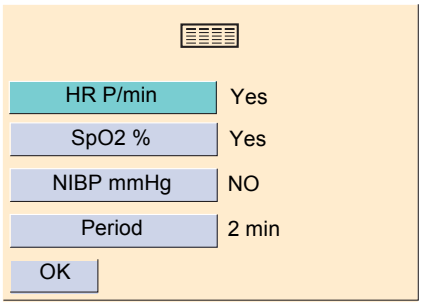


Fig. 4.12 Table settings

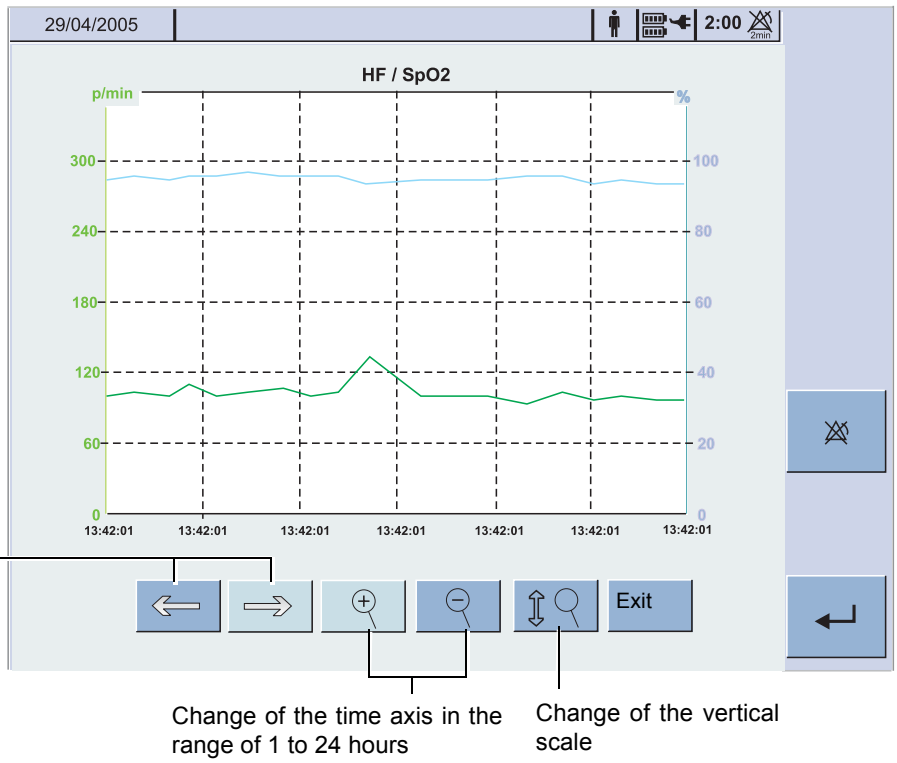
Table Settings

When "NIBP Measure" is selected for the "Period" parameter, the selected values are recorded for every NIBP measurement.

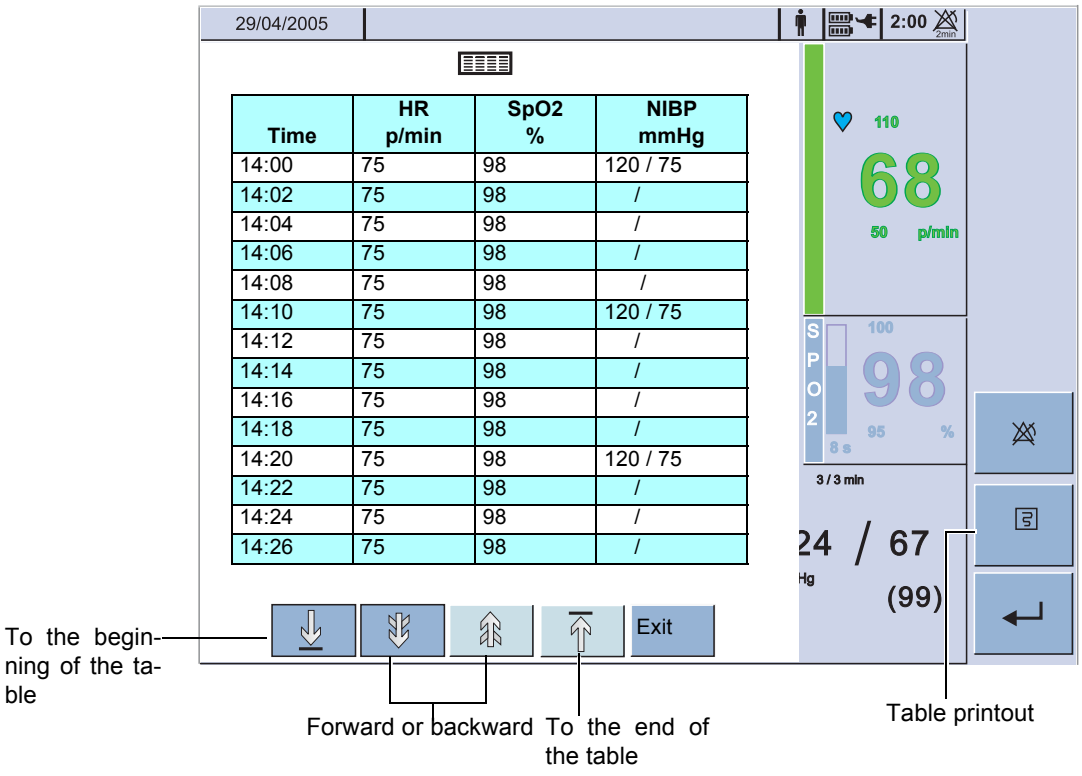
1. Select the required table values with Yes.
2. Select the desired recording period.
3. Confirm with OK. The trend display is opened.

Art. no.: 0-48-0060 Rev.: a

Trend Display for HR/SpO$_2$ Curves

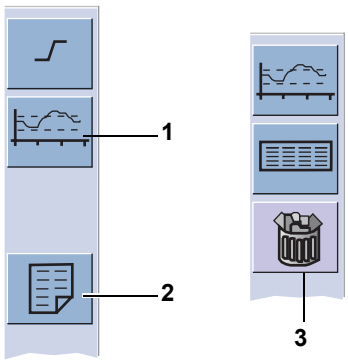


Trend Table



Art. no.: 0-48-0060 Rev.: a

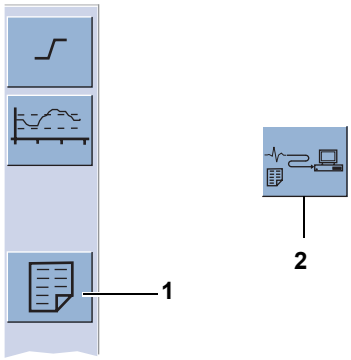
4.6.2 Deleting the Trend Memory



1. Press the navigation button.
2. Press the function key **Edition**.
3. Press the **trend** function key (**1**).
4. Press the **delete** function key (**3**).
5. Confirm with ✓ or cancel with ✗.

Fig. 4.13 Deleting trend data

4.6.3 Transmitting the Event Memory



1. Press the navigation button.
2. Press the function key **Edition**.
3. Press the **memory** function key (**1**).
4. Transmit the data by pressing the **transmission** function key (**2**).
5. To cancel the transmission, press ✗.

Fig. 4.14 Transmitting trend data

Art. no.: 0-48-0060 Rev.: a

5 Defibrillation

5.1 Rules and Safety Notes

Observe the following guidelines to ensure successful and safe defibrillation. Otherwise the lives of the patient, the user and bystanders are in danger.

⚠ DANGER

- ▲ The patient must:
  - – **not** come into contact with other persons during defibrillation.
  - – **not** come into contact with metal parts, e.g. bed or litter, or be positioned on wet ground (rain, accident in swimming pool), to prevent unwanted pathways for the defibrillation current, which may endanger the assistants.
- ▲ Do not allow the defibrillation electrodes to come into contact with other electrodes or metal parts which are in contact with the patient.
- ▲ The patient's chest must be dry, as moisture causes unwanted pathways for the defibrillation current. For safety, wipe off flammable skin cleansing agents.
- ▲ Owing to the high currents, there is a risk of skin burns at the site of the electrodes. This is why the electrodes must not be placed on or above:
  - – the sternum, clavicle or mamillas
- ▲ Immediately prior to the shock, the heart massage (CPR) and artificial respiration must be stopped and bystanders must be warned.
- ▲ Defibrillating a patient with an implanted pacemaker is likely to impair the pacemaker function or cause damage to the pacemaker. For this reason, do not apply the defibrillation electrodes in the vicinity of the pacemaker, have an external pacemaker at hand, and check the implanted pacemaker for proper functioning as soon as possible after the shock.

⚠ CAUTION

- ▲ Equipment damage! Sensors and devices that are not defibrillation proof must be disconnected from the patient before a shock is triggered.

Art. no.: 0-48-0060 Rev.: a

5.1.1 Additional Safety Notes for SAED Mode

In addition to the guidelines set forth in section 5.1, the following rules must be observed when using an SAED, as failure to do so may compromise the success of the defibrillation or endanger the patient's life.

⚠WARNING

- ▲ The user is committed to verify the prerequisites for the use of the SAED by checking for lack of consciousness, lack of breathing and lack of circulatory signs using the ABCD system (BLS algorithm).
- ▲ The device must only be used if the following symptoms are found:
  - non-responsive
  - no respiration
  - no pulse
- ▲ If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.
- ▲ To ensure correct analysis of the heart rhythm, the patient must lie as still as possible and must not be touched, as this can lead to incorrect analysis results due to artefacts.
- ▲ If, in SAED mode, the ECG signal changes such that the shock is not recommended, the shock delivery is automatically blocked.

5.1.2 Defibrillating Children

⚠WARNING

- ▲ Please note that less energy is needed for children.
  For the first defibrillation of infants and small children using biphasic shock, approx. 1 joule/kg body weight is released. An increase to 2 joules/kg body weight is possible when the defibrillation is repeated.
- ▲ For the defibrillation of children, the pediatric clip-on electrodes must be attached to the paddles or pediatric pads must be used.

Art. no.: 0-48-0060 Rev.: a

5.2 General Function

- The DEFIGARD® 5000 works with biphasic pulsed defibrillation impulse. Depending on the factory settings, the device either switches automatically from synchronized to non-synchronized defibrillation or the mode has to be changed manually using the **Sync** button.
- The required energy for a successful defibrillation depends on the patient's age, thickness of the tissue and constitution. For emergency medical treatment, AHA/ERC recommend (biphasic impulse):
  - 1st shock with 90 joules; if unsuccessful
  - 2nd shock with 130 joules; if unsuccessful
  - 3rd shock with 180 joules
- When a patient cable is connected, you can select in the ECG menu if the ECG should be recorded via the separate ECG electrodes or the defibrillation electrodes. You can select a higher energy value while the defibrillator is charging. The device will charge to the new level. It is not possible, however, to reduce the charged energy. In this case, the stored energy will be discharged internally and you will have to recharge the defibrillator.

5.2.1 Activating the Manual or Automatic Defibrillation Mode

When the device is switched on, it selects the defibrillation mode based on the connected electrodes.

- Paddles = manual defibrillation
- Spoons = manual defibrillation
- Adhesive electrodes = manual or automatic defibrillation (configurable)

You can switch from automatic to manual defibrillation by pressing the relevant softkey.

5.2.2 Manual Defibrillation - Procedure

1. Charge of the required energy with
   - paddles via the energy selection switch and the red charging/release button
   - adhesive electrode or spoon via keyboard
2. Release of the shock with
   - paddles via both red charging/release buttons
   - adhesive electrode and spoon via shock button on the device

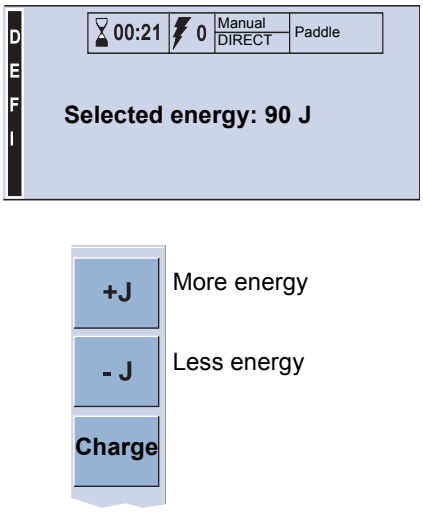


Fig. 5.1 Defibrillator window

Art. no.: 0-48-0060 Rev.: a

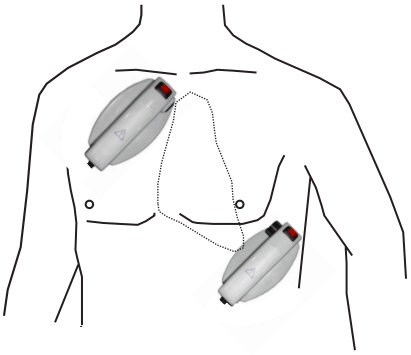
5.3 Manual Defibrillation Using Paddles

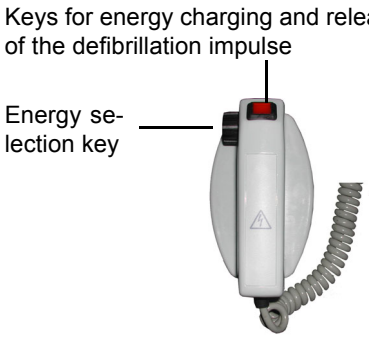
⚠ DANGER

▲ Delivering a shock to a patient normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in section 5.1.

▲ Electric shock hazard! Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.

- The defibrillation shock can be triggered only when the electrodes are applied to the patient and the skin resistance does not exceed a certain level. Otherwise the energy will be discharged internally when the shock is released!
- When the shock is not delivered within 20 s of charging, it will be discharged internally.





1. Remove the paddles from their compartments.
2. Carefully dry the paddles and the handles in particular, if they are wet.
3. Apply an ample amount of electrode cream to the paddle surfaces.
4. Apply the paddles as shown in Fig. 5.2:

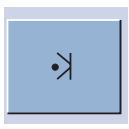
STERNUM: right sternal edge at the level of the 2nd intercostal space

APEX: left axillary line at the level of the 5th intercostal space

5. Select the required energy via the energy selection button.
6. Initiate charging by pushing one of the red buttons on the paddles. The bar diagram shows the energy charging process.
7. Do not touch the patient any more and warn all those present.
8. As soon as the charging process is completed,
   – a beep sounds
   – the message "Defibrillator ready" is displayed
   – the two shock keys on the paddles light up
9. Press the paddles firmly down onto the thorax.
10. Simultaneously press both buttons on the paddles.
    After delivery of the shock, the audio signal stops and the recorder starts (if configured). The recording can be stopped at any time by pressing the green button on the paddle or the button on the device (see "recording" section).
11. Monitor the patient's ECG.
12. When no further shocks are required, switch the energy selection button back to "0" and turn the device off.
13. Finish the therapy. (See page 60.)

Fig. 5.2 Paddle application

5.3.1 Marking Events



Each time you push the event button, the menu with your event texts will appear. You can select one of these texts with the softkey and this text will be recorded in the data report with the time of day.

The key texts are configurable.

Fig. 5.3 Event button

Art. no.: 0-48-0060 Rev.: a

5.4 Manual Defibrillation Using Pads

⚠ DANGER

- ▲ Delivering a shock to a patient with normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in sections 5.1 and 5.2.
- ▲ Electric shock hazard! Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.

5.4.1 Applying the Pads

⚠ CAUTION

- ▲ Only use the pads up to their expiration date. Please note that the indicated expiration date only applies if the vacuum pack is intact.
- ▲ The pads are pre-gelled, so there is no need to use extra contact agent.
- ▲ Do **not** reuse the pads.

Adult and Pediatric Electrodes

Large electrodes

The large electrodes are intended for adults and children from a body weight of 25 kg.

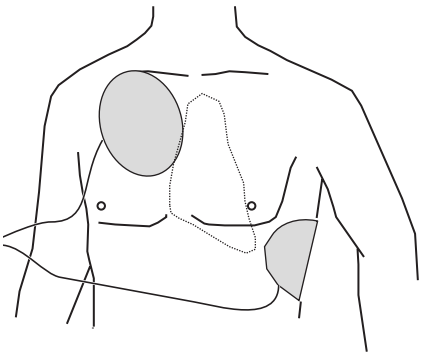
Small electrodes

The small electrodes are intended for children with a body weight under 25 kg.

Applying the Electrodes

⚠ WARNING

- ▲ Good contact between the skin and the adhesive electrodes must be ensured. Suntan oil, sand or salt reduce the adhesive quality.
- ▲ The applied pads must have good contact with the patient's skin, and air bubbles under the pads must be avoided. To do so, stick on one end of the pad, then smooth it out to the other end.



1. Clean and dry the application points for the electrodes (Fig. 5.4). Shave if the patient's chest is hairy. Only clean the skin by vigorously rubbing it with a dry cloth.
2. Apply one electrode above the right nipple. Do not apply it on the clavicle (uneven).
   STERNUM: right sternal edge at the level of the 2nd intercostal space
3. Apply the other electrode slantwise below the left breast as illustrated in Fig. 5.4.
   APEX: left axillary line at the level of the 5th intercostal space
4. Make sure that the connections are positioned on the outside so they do not hinder heart massage (CPR).

Fig. 5.4 Electrode application points

Art. no.: 0-48-0060 Rev.: a

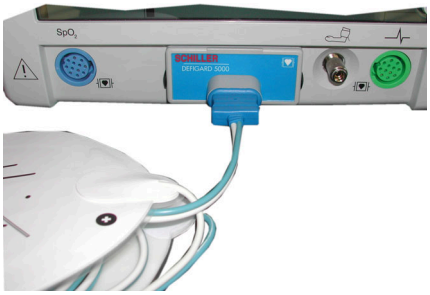
5.4.2 Checking the Electrodes

If the resistance between the skin and an electrode is too high, the message CONNECT THE ELECTRODES is issued. Proceed as follows:

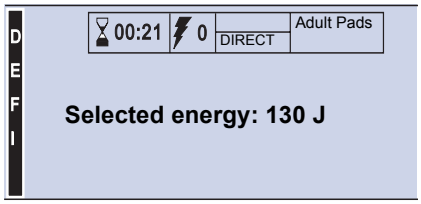
1. Alternately press the electrodes/pads down firmly and check when the message disappears. Carefully press that pad onto the patient's skin once again.
   If the message does not disappear,
2. remove both defibrillation electrodes
3. wipe rests of contact agent off with a cloth
4. shave the two application points to remove the epidermal skin layer
5. apply new defibrillation pads to these points

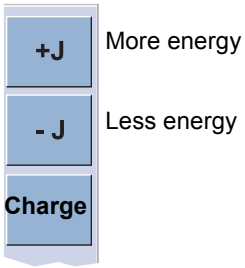
Art. no.: 0-48-0060 Rev.: a

5.4.3 Manual Defibrillation Using Pads - Procedure



1. Connect the electrode cable to the adapter.
2. When the device is started in SAED mode, switch to manual mode by pressing the  softkey. A safety discharge is first carried out and the energy is set to 130 J.





3. Select the energy via the softkeys.
4. Initiate the energy charging by pressing "Charge".

⚠ DANGER

▲ Danger of electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.

5. Trigger the shock by pressing the button  .

Fig. 5.5 Manual defibrillation using pads

Art. no.: 0-48-0060 Rev.: a

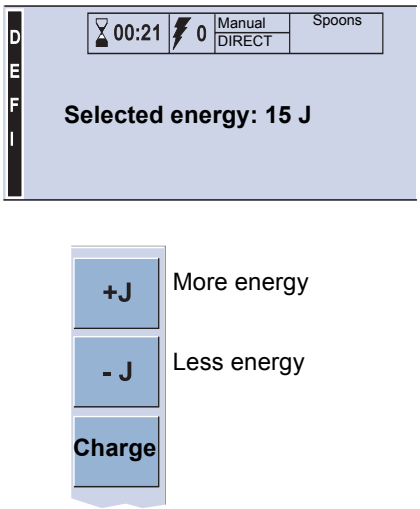
5.5 Internal Defibrillation

WARNING

▲ Patient hazard! Use only sterilised electrodes for internal defibrillation. Sterilise internal electrodes before each use (see section 10 "Maintenance").

Spoon-shaped electrodes whose contours must match the dimensions of the heart are used for internal defibrillation. The electrode surface must make full contact with the heart. Internal electrodes are available in four different sizes (see order information in section 12). As the electrodes are in direct contact with the heart, less energy is required than for external (transthoracic) application. Therefore, the defibrillator does not accept energy settings above 30 joules. The following energy levels are available: 2, 4, 6, 8, 15, 30 joules.

1. Connect the spoons' electrode cable to the adapter.
2. Position the spoons on the heart.



3. Select the energy using the **+/- J** keys.
4. Initiate the energy charging by pressing "Charge".

DANGER

▲ Danger of electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.

5. Trigger the shock by pressing the button  .

Fig. 5.6 Defibrillator window

Art. no.: 0-48-0060 Rev.: a

5.6 Synchronised Defibrillation

⚠WARNING

▲ Erroneous triggering, interpretation hazard.
- For synchronised defibrillation, the ECG electrodes should be applied as far from the defibrillation electrodes as possible (e.g. on the limbs).
- Use only silver/silver-chloride electrodes, if you acquire the ECG via separate ECG electrodes. These electrodes prevent polarisation voltages which may be caused by the defibrillation shock, resulting in an ECG trace on the monitor screen or recording that simulates cardiac arrest.

⚠ CAUTION

▲ Disturbed ECG trigger! Signal Signal noise may disturb the ECG signal and cause artefacts. This must be considered chiefly in the synchronised mode and in demand pacing. For this reason, the following should be observed:
- Do not touch the device during defibrillation to prevent electrostatic noise
- Keep the patient cable away from power cords, transformers etc.

▲ To achieve adequate ECG signal quality for reliable triggering, ensure that
- the ECG signal is free of artefact
- there are no major fluctuations in amplitude
- the displayed trigger pulses are positioned exactly over the R-wave

5.6.1 Switching to Synchronised Defibrillation

The mode can be changed manually or automatically.

1. Go to the defibrillator window using the navigation key.
2. Press the key. The **Sync** key appears.
3. Using the **Sync** key, select synchronised or direct defibrillation. The setting **Synchro** (**1**) or **Direct** is displayed in the defibrillator window.

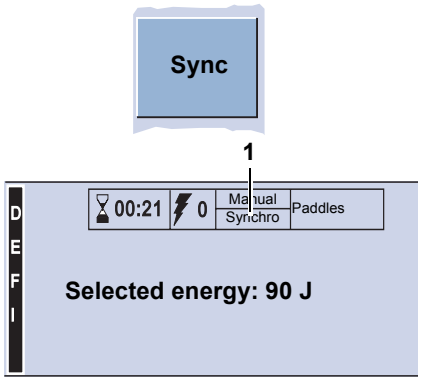


Fig. 5.7 Switching to/display of synchronised defibrillation

Art. no.: 0-48-0060 Rev.: a

5.6.2 Synchronised Defibrillation – Procedure

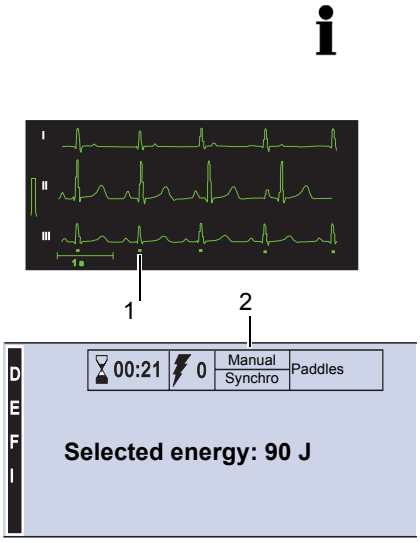


Fig. 5.8 Synchronised defibrillation

For synchronised defibrillation, the defibrillation shock is delivered in synchronisation with the heart action, as the heart is still working. As a prerequisite, the patient's ECG signal must be supplied to the defibrillator. After the physician has triggered the defibrillation shock, the trigger signal for the actual shock delivery will be derived from the subsequent QRS complex (25 ms after the trigger mark on the monitor screen **(1)**).

The defibrillation mode can be switched automatically or manually between unsynchronised and synchronised, depending on the factory settings (this setting can be found in the Defibrillator menu - see page 66, section 9.1.5).

When the switchover is **automatic**, the DEFIGARD® 5000 switches to the synchronised mode when it detects a QRS complex. If no QRS complex is detected for more than 3 seconds, the message **SYNCRO** (**2**) is replaced by **SYNCHRO END** and an audible signal sounds. After 3 more seconds, it switches from **SYNCHRO** (**2**) to **DIRECT** defibrillation.

With devices set to **manual switch**, the mode is changed using the key. However, if the device does not detect a QRS complex in the synchronised mode, the shock will be delivered directly after 6 seconds. We recommend performing synchronised defibrillation **with pads** and at the same time acquiring the ECG signal via the pads. As an alternative, the ECG can be acquired with ECG electrodes. You select the signal source with the source button in the ECG menu.

Synchronised defibrillation using paddles

When using paddles for synchronised defibrillation, you can configure if the ECG must be recorded via separate ECG electrodes (**Synchro using paddle - No**) or if the recording can be done using either separate ECG electrodes or the paddles (**Synchro using paddle - Yes)**. Defibrillation with pads is described on page 42; defibrillation with paddles on page 41, and the application of ECG electrodes on page 42. Check that with each QRS complex

- the QRS beep sounds
- the trigger marks (**1** - Fig. 5.8) and the "QRS blip" appear

Be aware that after initiation of the shock the actual shock will be released with the next trigger signal derived from the ECG.

Art. no.: 0-48-0060 Rev.: a

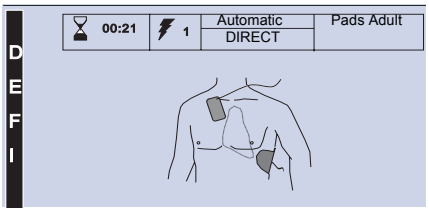
5.7 Semiautomatic Defibrillation

⚠ DANGER

- ▲ Delivering a shock to a patient normal heart rhythm may induce ventricular fibrillation. For this reason, first read the general rules and safety information in sections 5.1 and page 5.1.139.
- ▲ Electric shock hazard! Turn off the device before exchanging the defibrillation electrodes; exchanging the electrodes on a charged defibrillator initiates an internal safety discharge.
- ▲ Do not use the anterior-posterior electrode placement for semiautomatic defibrillation.
- ▲ If, in the course of treatment, a patient spontaneously regains consciousness, a defibrillation shock that may have been advised just before must not be delivered.
- ▲ During HF surgical interventions, ECG analysis is not permitted in the semiautomatic mode.

5.7.1 Semiautomatic Defibrillation (SAED) – Procedure

The user is guided through all operation steps by spoken and displayed instructions.



The SAED mode is automatically activated when the adapter for adhesive electrodes is inserted. (See page 66, section 9.1.5.)

After start-up, the user is prompted by a flashing symbol to connect the pads. When the analysis key is pressed, there is a spoken message that the electrodes should be connected to the patient, if this has not been done yet. After this, the user is advised to stay clear of the patient. The analysis takes approximately 10 seconds.

Device detects a shockable rhythm

If the analysis program detects a shockable rhythm, the defibrillation energy is charged and the user is prompted to deliver the shock. Shockable rhythms are:

- Ventricular fibrillation
- Ventricular tachycardia with a rate exceeding 180 p/min

Even if the device detects a shockable rhythm, a shock must only be delivered if lack of breathing and lack of circulatory signs have been established.

If the shock is not successful, the device automatically charges the defibrillation energy for a second or a third shock.

The following standard energy levels are preset:

Shock	Adults	Neonates
1	130 joules	15 joules
2	130 joules	30 joules
3	150 joules	50 joules

The SCHILLER after-sales service can adjust different energy settings.

Art. no.: 0-48-0060 Rev.: a

Shock unsuccessful

If also the 3rd shock is unsuccessful, **the device** prompts the user to:

- carry out alternately artificial respiration and heart massage.
- start a new ECG analysis after one minute. Depending of the configuration, this new analysis can be started automatically.

Shock successful

After a successful shock, **the device** prompts the user to:

- check the patient's respiration and circulation and
  - if **no** signs of circulation are present, to alternately carry out artificial respiration and heart massage
  - if signs of circulation are present, to move the patient to the lateral position

Device detects no shockable rhythm

If the analysis program does not detect a shockable rhythm, the device informs the user about the further steps:

- informs that no shock is required
- prompts the user to check the patient's respiration and circulation
  - if **no** signs of circulation are present, to alternately carry out artificial respiration and heart massage
  - if signs of circulation are present, to move the patient to the lateral position
  - after one minute, prompts the user again to start a new ECG analysis. Depending on the configuration, this new analysis can be started automatically.

Art. no.: 0-48-0060 Rev.: a

Voice Support in SAED Mode

When the device is switched on, it carries out a self-test and indicates the software and hardware version. The following instructions will be spoken by the device:

Language	Display	Note
Stick electrodes on bare and dry chest	CONNECT THE ELECTRODES!	Technical alarm: Electrodes not yet applied. The message disappears as soon as the electrodes are correctly applied and the resistance is below 250 Ohm.
Poor connection; press the electrodes	PRESS THE ELECTRODES	Technical alarm: The contact between the electrodes and the skin is not sufficient. The patient resistance is in the range of 250 to 400 Ohm.
Press the green button	PRESS THE GREEN BUTTON	Heart rhythm analysis is started.
Do not touch the patient. Analysis in progress.	DO NOT TOUCH THE PATIENT ANALYSIS IN PROGRESS	
Motion detected; stop the motion	MOTION DETECTED STOP MOTION	Technical alarm: The patient was moved during the analysis and the device could not carry out the analysis.
Device recommends a shock		
Do not touch the patient, charging	DO NOT TOUCH THE PATIENT, CHARGING IN PROGRESS	
Stand clear of patient, press orange button	PRESS ORANGE BUTTON TO SHOCK	
Device does not recommend a shock		
Shock not recommended		
Check for signs of circulation	CHECK FOR SIGNS OF CIRCULATION	
If no signs of circulation, give two breaths, then 15 chest compressions - continue.	15 CHEST COMPRESSIONS THEN 2 RESCUE BREATHS - CONTINUE	

Art. no.: 0-48-0060 Rev.: a

5.7.2 Defibrillation - Procedure

When the device is switched on, it gives spoken and displayed instructions up to the defibrillation. Exactly follow the instructions.

Step 1

Switching on and Preparing the Device

1. Insert the adapter for the adhesive electrodes.
2. Switch on the device by pressing the green button.
3. Check the state of the patient.
4. Connect the electrode cable to the adapter.
5. You are prompted to apply the electrodes.
6. Apply the defibrillation electrodes (see section 5.4.1, page 42). The message CONNECT THE ELECTRODES is switched off as soon as the device measures an acceptable electrode resistance. If it is not switched off, see section 5.4.1.

Fig. 5.9 Switch unit on

Step 2

Analysis

7. You are prompted to start the analysis.
8. Press the blue button. You are prompted not to touch the patient any more.

If the device detects ventricular fibrillation or ventricular tachycardia with a heart rate exceeding 180 pulse/min, shock delivery follows (see step 4 - Shock Delivery); otherwise continue with Step 4, Cardiopulmonary Resuscitation.

Fig. 5.10 Analysis

Art. no.: 0-48-0060 Rev.: a

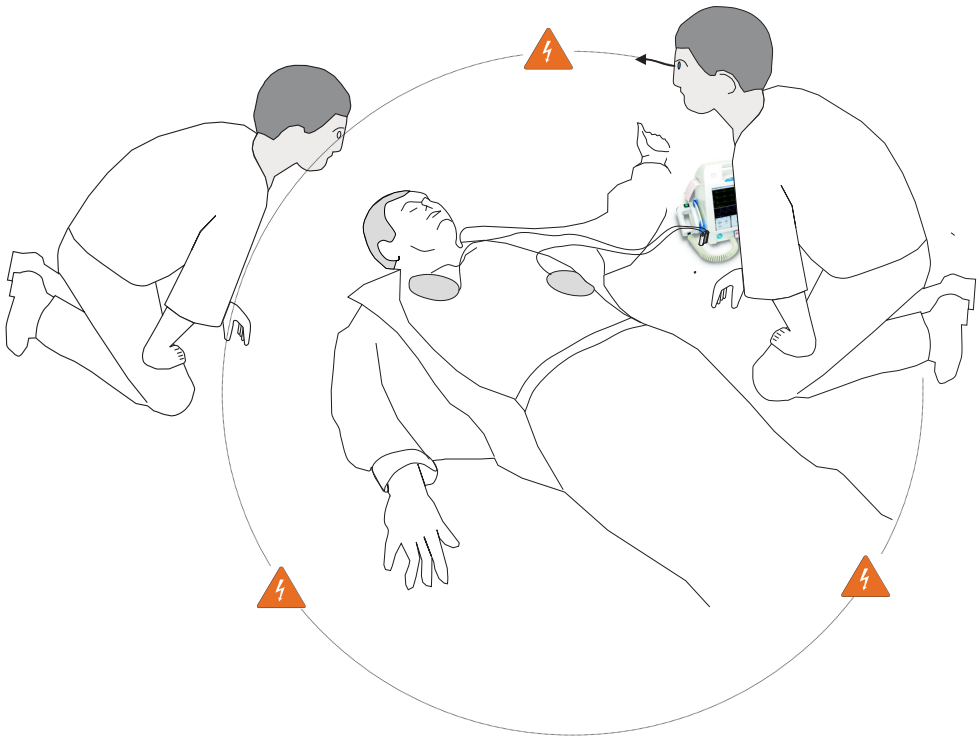
Step 3

Shock Delivery

As soon as the energy for a shock is charged, the device prompts the user to deliver the shock by pressing button 3.

▲ Danger of electric shock!

- Do not, under any circumstances, touch the patient during shock delivery.
- Make sure that the patient does not touch any conducting objects.



9. Deliver the shock by pressing the button  .

   After shock delivery, the device checks if the shock has been successful by carrying out an automatic analysis. If the shock was **not** successful, the steps **2** to **3** are repeated once or twice, whereas the preset energy levels for the 2nd and 3rd shocks are charged. Then step **4** follows.

Step 4

Cardiopulmonary Resuscitation

Prompt to check the patient's respiration and circulation.

10. Check the patient.
    - If no sings of circulation are present, carry out cardiopulmonary resuscitation. Alternate between two breaths and 15 cardiac massages for one minute. After one minute, the device begins again with Step 2, Cardiopulmonary Resuscitation.
    - If circulatory signs are present, move the patient onto his or her side.

Art. no.: 0-48-0060 Rev.: a

5.8 Defibrillator Error Messages

Alarm	Cause	Remedy
SYNCHRO END	• No pulse	➜ Check ECG
BAD CASSETTE	• Wrong cassette connected • Cassette has not completely locked into place	➜ Use the correct cassette ➜ Lock the cassette into place

Art. no.: 0-48-0060 Rev.: a

6 Pacemaker

6.1 Pacemaker Function

The pacemaker is the module for external transthoracic stimulation of the heart.

The pacemaker offers two modes of operation, demand and fixed-rate pacing. The overdrive mode can be used to correct conditions of tachycardia. In demand mode, the pacemaker requires an ECG signal for synchronisation.

The same, large-surface adhesive electrodes used for defibrillation are also employed for pacing. They ensure good electrical contact with the skin. These electrodes and a 40 ms square-wave pulse reduce painful muscle contractions provoked by excessive current density.

It is not possible to simultaneously connect pads for defibrillation and for pacing.

Pacer rate, pulse width and current are checked when the device is turned on and during operation; therefore a functional test of the pacemaker module is not necessary.

6.1.1 Fixed-Rate Mode (Fix)

In this operating mode, the module delivers pacing pulses with user-defined current at a user-defined rate. The selected rate remains constant and is not affected by intrinsic actions of the patient's heart. This is the preferred mode for cases of cardiac arrest.

6.1.2 Demand Mode

In demand mode, the pacemaker does not deliver pacing pulses as long as the patient's intrinsic heart rate exceeds the set pacing rate. When the heart rate drops below the pacing rate, the pacemaker starts emitting stimulation pulses. This can only be ensured by continued monitoring of the ECG. The pacemaker receives the necessary ECG signal via the ECG electrodes. If the module is not able to reliably identify QRS complexes, it will stimulate the heart permanently in demand mode.

The demand mode is the recommended pacing mode when the patient is at risk of developing bradycardia or even asystole as a result of a critical event. As the pacemaker function is controlled by the patient's ECG, the harmful competition between intrinsic and external stimulation, which could induce ventricular fibrillation, is excluded.

6.1.3 Overdrive Mode

In the overdrive mode, the pacer will operate at three times the selected rate.

This operating mode should be selected to correct conditions of tachycardia. The heart is stimulated with a rate that is above the intrinsic heart rate. At the end of the intervention, the heart rate should return to a normal rhythm.

Art. no.: 0-48-0060 Rev.: a

6.2 Safety Notes

WARNING

▲ **Shock hazard!**
Never touch the pads or the patient's body near the pads while the pacemaker is in use.

CAUTION

▲ **Patient hazard, equipment failure**!
Equipment delivering electrical energy to the patient at the same time as the pacemaker can disturb the pacemaker function. Particularly HF surgery equipment used on a pacemaker patient may cause interference, preventing the detection of QRS complexes. In this situation, the pacemaker must be set to fixed-rate pacing (FIX). Also please note that leakage currents could be transferred to other electric circuits, interfering with the functioning of devices connected to these circuits.

▲ For safety reasons, the external pacemaker should be disconnected from the patient in this situation and an internal pacemaker should be used.

▲ Accessories, wearing parts and disposables that affect the safe use of the pacemaker and that are to be used in conjunction with the pacemaker must be tested for safety and approved by an authorised test laboratory.

6.3 Guidelines for the Application of External Pacemakers

These guidelines apply to all pacemakers, irrespective of type and manufacturer.

All electrical devices that deliver energy to patients in any form or have an electrically conductive connection to the patient are a potential source of danger.

As the user is responsible for the safe application of the devices, observance of the instructions given in the user manual and of the guidelines below is of utmost importance.

- Pacemakers must only be used under the supervision of qualified and authorised staff.
- Observe the user guide for the pacemaker's operation.
- The patient must not be left unattended during pacing.
- It is assumed that the patient's ECG is being monitored to be able to assess the effect of pacing.
- When positioning the patient, take care that no electrically conductive connections exist between the patient and earthed metal parts (puddles of water, for instance, are capable of conducting the electrical current). Although the pacer current output is required to be floating, this is an additional safety precaution to ensure that the pacemaker current pulse flows only between the pacemaker electrodes.
- Set all values for the pacemaker to position 0, or the lowest value.
- Position stationary pacemakers close to the patient.
- After each defibrillation, check that the pacemaker is functioning properly.

Art. no.: 0-48-0060 Rev.: a

6.3.1 Attaching the Pacer Pads

- The same electrodes used for defibrillation are also employed for pacing.
- For children with a body weight under 15 kg, pads with a surface of 28 cm^2 should be used.
- For children weighing more than 15 kg, pads with a surface of 78 cm^2 should be used.

The application of electrodes is detailed in section 5.4.1 on page 42.

Anterior-Posterior Placement

1. Apply the dorsal electrode (+) to the left scapular area and the precordial electrode (-) near the left lower sternal edge.
2. Connect the pace pads to the device.

If the dorsal electrode cannot be used, apply anterior-anterior placement.

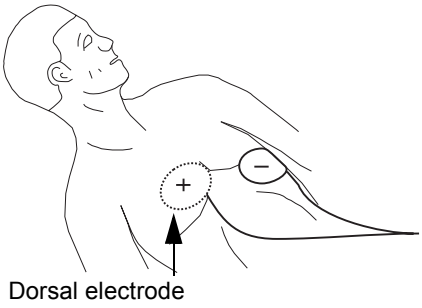


Fig. 6.1 Anterior-posterior placement

Anterior-Anterior Placement

1. Apply the “+” electrode on the right side below the clavicle and the “-” electrode to the left of the axillary line on a level with the 5th intercostal space so they do not hinder heart massage.
2. Connect the pace pads to the device.

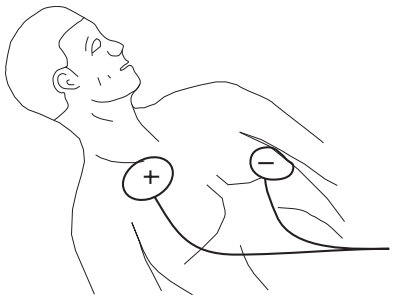


Fig. 6.2 Anterior-anterior placement

Art. no.: 0-48-0060 Rev.: a

6.4 Start-up of the Pacemaker

- The device can at any time be switched from defibrillation to pacing mode if required.
- When the pacemaker is switched on, the current value is set to 0.

6.4.1 Pacemaker Display

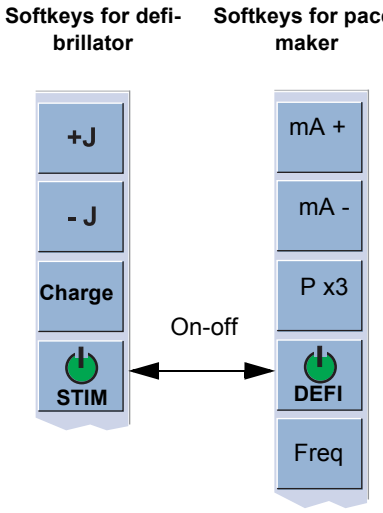


Fig. 6.3 DEFI and STIM softkeys

1. Select the defibrillator display using the navigation button.
2. Display the pacemaker function by pressing the STIM softkey .

The softkeys for the pacemaker settings (Fig. 6.3) and the pacemaker values are displayed.

6.4.2 Selecting Pacemaker Mode

1. Select the defibrillator display using the navigation button.
2. Press the navigation button. The **Mode** softkey is displayed.
3. Press the **Mode** key to select the operational mode **Fix** or **Demand.**
4. The operational mode is displayed in the defibrillation window **(1)**.

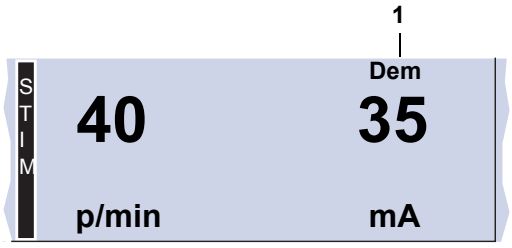


Fig. 6.4 Pacemaker mode

Art. no.: 0-48-0060 Rev.: a

6.4.3 Pacemaker Settings Operational Mode Fix

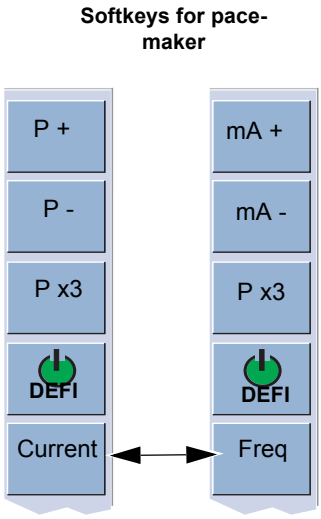


Fig. 6.5 Softkeys for pacemaker

1. Display pacemaker and select operational mode fix. (See page 57.)
2. Set the pacer rate using the function keys **P +/-**.
3. Display the keys for the pacer output by pressing the **Current** softkey.

WARNING

▲ **Shock hazard!**
Never touch the pads or the patient's body near the pads while the pacemaker is in use.

4. Set the pacer output using the buttons **mA +/-** until the heart will certainly react on the stimulation.
5. After completion of the therapy, set the pulse rate and current to the minimum value before carefully tearing off the electrodes from the patient.

6.4.4 Demand Mode

1. Record an ECG with patient cable as described in section on page 25.
2. Attach the pacer pads (See page 56.)
3. Display pacemaker and select operational mode **Demand**. (See page 57.)

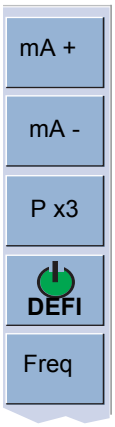
Fig. 6.6 Intrinsic heart rate indicator flashes

4. Increase the pulse rate using the button **P +** until the symbol on the display starts flashing. The pulse rate has now reached or slightly exceeded the intrinsic heart rate.
5. Increase the impulse current using the button **mA +** until the heart reacts to the stimulation (QRS complexes visible on the display).
6. Now set the required pulse rate using the **P +/-** keys.
7. When the therapy is finished, switch the pacemaker off and carefully remove the electrodes.

Art. no.: 0-48-0060 Rev.: a

6.4.5 Overdrive Mode

Softkeys for pacemaker



1. Start the pacemaker as described in section 6.4 on page 57.
2. Set the pacemaker mode to Fix. The **P x3** softkey is displayed.
3. Keep **P x3** pressed while increasing the pulse current using the button **mA +** until the heart has reached the pacemaker's rate.
4. Now let the **P x3** key go. The heart should continue to beat with a normal heart rate.
5. Finish the therapy.

Fig. 6.7 Softkeys for pacemaker

Art. no.: 0-48-0060 Rev.: a

7 Finishing the Therapy

1. Switch the device off as soon as the therapy is finished (keep the button pressed for approx. 2 seconds).
2. Disconnect the plug of the electrode line.
3. Carefully remove the electrodes from the patient's skin.
4. Discard the disposable pads immediately after use to prevent their reuse (hospital waste).
5. Sterilise the spoon electrodes immediately after use.
6. Clean the device as described in section 10.

Art. no.: 0-48-0060 Rev.: a

8 Intervention Summary

To document the intervention, the ECG (30 minutes, 1 lead) and the intervention (500 events max.) are saved.

Overview of events documented with date and time:

- Power on
- Start of analysis
- Analysis result
- Defibrillator charging
- Defibrillation shock
- Internal discharge
- Switchover to manual operation
- Electrode alarm
- "Battery low" alarm
- Activation of a vital signs module
- Deactivation of a vital signs module
- Asystole alarm (manual mode)
- Fibrillation/flutter alarm (manual mode)
- Event button

Art. no.: 0-48-0060 Rev.: a

8.1 Printing Curves and Measured Values

The curves and parameter settings to be printed and the printing length are described on page 66, section 9.1.5.

Fig. 8.1 Start/stop printout key

1. Press the **Start/stop printout** key. If no or a 3-lead ECG cable is connected, the set curves are printed directly. With a 4 - or 10-lead patient cable, the keys for the available print options are displayed.
2. Start the printout by pressing the respective **print option** key.
3. The printout can be stopped at any time using the start/stop printout key.

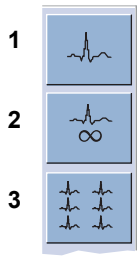


Fig. 8.2 Print option keys

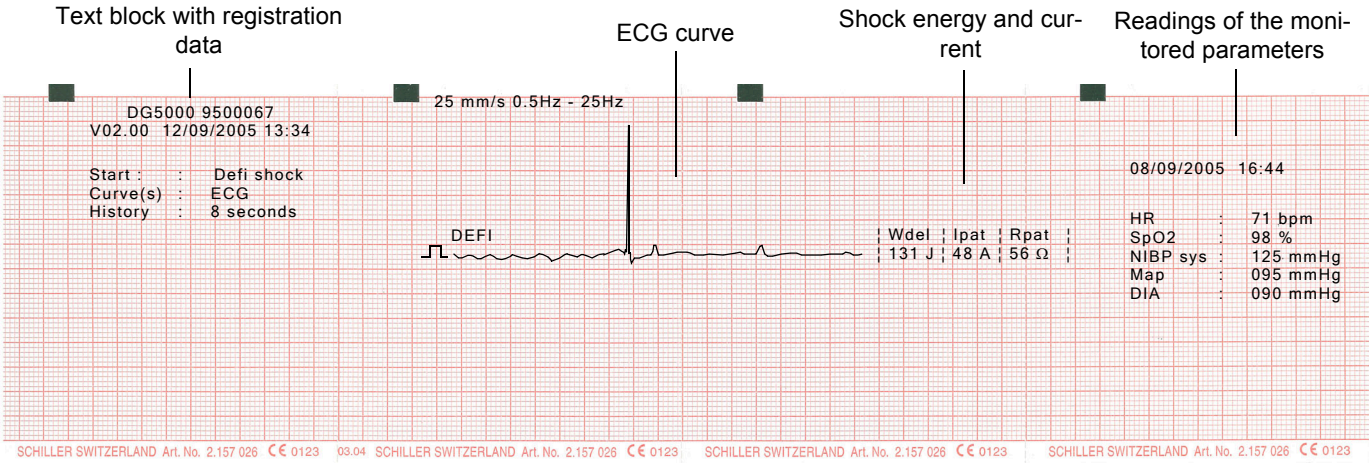
Print Options

(1) Printout of the set curves with set printing length and parameter values. (The print settings are described in section 9.1.5.)

(2) Printout of the set curves until the printout is stopped using the start/stop key, and the parameter values. (The print settings are described in section 9.1.5.)

(3) Printout of all ECG curves and measured values.

8.1.1 Example of a Defibrillator Shock Printout



8.1.2 Printer Error Messages

Alarm	Cause	Remedy
RECORDER: NO PAPER!	• No paper in the printer	➜ Insert paper
RECORDER: DOOR OPEN!	• Printer door is open	➜ Close the door
RECORDER: TIME OUT!	• Paper jam in the printer	➜ Remove the paper jam

Art. no.: 0-48-0060 Rev.: a

9 Default and User-Defined Thresholds

For the monitoring of vital parameters, physiological alarm thresholds are preset in the DEFIGARD® 5000, which are activated when the device is turned on. The device distinguishes between **default** and **user-defined thresholds** for adults and neonates. The user-defined thresholds can be changed in the respective menus; the default thresholds are changed in the **device configuration** menu (see page 67, section 10).

All changes are saved. When the device is put into operation for the first time, the user-defined thresholds are identical with the default thresholds.

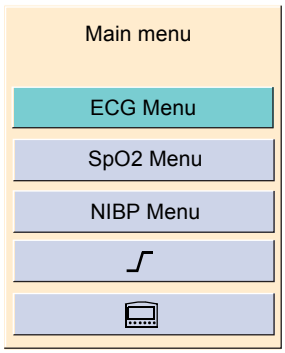


Fig. 9.1 Main menu

1. Press the navigation button. When the navigation button is pressed twice, the main menu is directly opened and step 2 is dropped.
2. Press the **Menu** softkey. The main menu is displayed.
3. Select, display and modify the menu by turning and pressing the button.
4. To access the threshold menu directly, press .
5. The time, volume and printer configuration can be set via the unit settings button .

Art. no.: 0-48-0060 Rev.: a

9.1 User-Defined Thresholds

The settings are detailed in section 4. The following table gives an overview of the user-defined thresholds, with the factory defaults in bold letters.

9.1.1 ECG Menu

The thresholds are only displayed after the user's threshold values have been opened once in the threshold values menu .

Menu	Parameter	Value
ECG	Number of curve(s)	0 / 1 / 2 / **3** / 6 /12
	Lead channel 1	Defi/**I, II, III**/aVR, aVL, AVF/V1, V2, V3/V4, V5, V6
	Lead channel 2	[a]Defi/**I, II, III**/aVR, aVL, AVF/V1, V2, V3/V4, V5, V6
		0.25/**0.5**/1/2 cm/mV
		**HR** ← **ECG**/HR ← SpO2
	QRS beep	Off/Low/**Medium**/High
	Speed	**25**/50 mm/s
	Patient	**Adult**/Neonate
	High threshold	(**140**...300)/Off
	Low threshold	Off/**60** (range 30...125)

a. The "Defi" option is only available when a patient cable and an adapter module with defibrillation electrodes are connected.

9.1.2 SpO_2 Menu

The threshold values are only displayed after the user's threshold values have been opened once in the threshold values menu .

Menu	Parameter	Value
SpO_2	SpO_2 curve	Yes/no
	Average Cycles	**8**/16 seconds
		**HR** ← **ECG**/HR ← SpO2
	Speed	**25**/50 mm/s
	Patient	**Adult**/Neonate
	High pulse threshold	(**130**...250)/Off
	Low pulse threshold	Off/**50** (range 30...125)
	High SpO_2 threshold	**100**/Off (range 55...250)
	Low SpO_2 threshold	Off/**85** (range 50...99)

Art. no.: 0-48-0060 Rev.: a

9.1.3 NIBP Menu

The thresholds are only displayed after the user's threshold values have been opened once in the threshold values menu .

Menu	Parameter	Value
NIBP		Manual, Continuous or cycle of 1 / 2 / 3 / 5 /10 /15 /20 / 30 / 40 / 90 minutes
	Patient	**Adult**/Neonate
	Unit	**mmHg / kPa**
	High SYS threshold	**180** (70...250)
	Low SYS threshold	**70** (Off/50...225)
	High MAP threshold	**160** (25...250)
	Low MAP threshold	**50** (Off/20...245)
	High DIA threshold	**110** (15...200)
	Low DIA threshold	**40** (Off/10...195)

9.1.4 User-Defined Thresholds Menu

The thresholds menu is accessed via the menu or threshold key . The values can be selected and changed using the navigation key.

Menu	Parameter	Min.	Max.	Unit
ECG	HR	70	**150**	**p/min**
SpO2	PULS	50	**130**	**p/min**
	%	85	100	%
NIBP	SYS	70	**180**	**mmHg**
	Map	**50**	**160**	**mmHg**
	DIA	**40**	**110**	**mmHg**

With the **Default** key, the default threshold values are copied into the operator table.

With the key, all values are deactivated.

With the Quick Set key, all values are derived from the current measured values.

- Low threshold = -20 %
- High threshold = +20 %

Exit the menu by pressing Enter.

Fig. 9.2 Softkeys in the threshold menu

Art. no.: 0-48-0060 Rev.: a

9.1.5 Unit Settings Menu

Access the unit settings menu via the menu or the button. The values can be selected and changed using the navigation button.

Menu	Parameter	Value	Note
	• Day	-	When the date and time are changed, the data in the trend memory is deleted.
	• Month	-	-
	• Year	-	-
	• Hour	-	-
	• Minute	-	-
	• Date format	DD/MM/YY or MM/DD/YY	-
	• Summer/winter time	Yes/no	-
	• Alarm sound	High, Medium, Low	-
	• QRS sound	High, Medium, Low, Off	-
	• Pace sound	High, Medium, Low, Off	-
	• Key sound	High, Medium, Low, Off	-
	• Language	High, Medium, Low, Off	-
	• Manual printing	ECG, Puls, ECG/ECG, ECG/ Puls	Selection of values to be printed on manual printouts
	• Alarm printing	ECG, Puls, ECG/ECG, ECG/ Puls, ECG/Alarm	Selection of values to be printed on automatic printouts (“Printing on alarm”)
	• Printing on alarm	No, HR only, All alarms	Alarm events which should trigger a printout
	• Printing on shock	Yes, No	
	• History	“No history” or “8 s”	Printout including 8 seconds before the printout trigger
	• Printing length (page)	2, 3, 4, 5, 6	Number of pages per printout
	• Lead change (page)	2, 3, 4	Length of lead printouts
Defibrillator	• Synchro modification	“Key” or “Automatic”	
	• Synchro at start	“Direct” or “Synchro”	
	• Synchro with paddles	Set to Yes or No	
	• Mode at start	“SAED” or “Manual”	
	• ERC protocol	1 or 3 min	
Demo mode	For demonstration only	Only accessible with a password	Display of curves and measured values without sensors

Art. no.: 0-48-0060 Rev.: a

10 Default Values

To change the default values, access the **DEVICE CONFIGURATION** menu as follows:

➜ Keep the navigation button pressed while switching on the device.

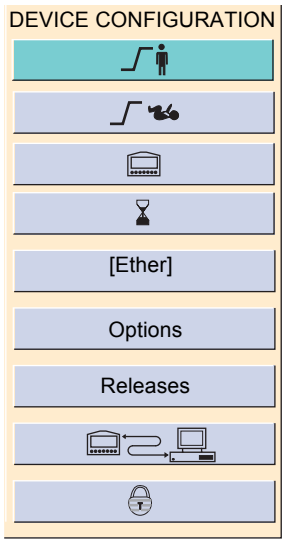


Fig. 10.1 DEVICE CONFIGURATION menu

Saving the Values

After the threshold values and parameters have been set, the device must be switched off.

10.1 Default Threshold Values for Adults

Menu	Parameter	Min.	Max.	Unit
ECG	HR	50	130	p/min
SpO2	PULS	50	130	p/min
	%	85	100	%
NIBP	SYS	70	180	mmHg
	Map	50	160	mmHg
	DIA	40	110	mmHg

10.2 Default Threshold Values for Neonates

Menu	Parameter	Min.	Max.	Unit
ECG	HR	50	130	p/min
SpO2	PULS	50	130	p/min
	%	85	100	%
NIBP	SYS	50	140	mmHg
	Map	40	120	mmHg
	DIA	30	100	mmHg

Art. no.: 0-48-0060 Rev.: a

10.3 Default Device Settings

10.3.1 Alarms

Menu	Parameter	Value
	• -4 % SpO2 alarm	Yes/no
	• Elec. fault with paddles	Yes/no
	• Physiological alarms	Locked/Not locked
	• 2' alarm rejection at start	Yes/no
	Permanent alarm switch-off	Yes/no This setting is not allowed in all countries
	• VF alarm in manual	Yes/no
	• Alarms in SAED	Yes/no
	• Defi ready in SAED	Yes/no

10.3.2 NIBP

Menu	Parameter	Value
NIBP	• CONT mode length	5 min (5 - 15 min)
	• Cycle after CONT mode	3 min (1 - 90 min)

10.3.3 Language

Menu	Parameter	Value
?	Language	Deutsch, English, Français, Italiano, Português, Español

10.3.4 Screen Colour

Menu	Parameter	Value
	Screen Colour	Colour 1, 2, 3

10.3.5 Mains Filter

Menu	Parameter	Value
Mains Filter	Mains filter	50, 60 Hz, None

10.3.6 Serial Number

Menu	Parameter	Value
Serial Nb	**Serial Nb**	Can only be changed by the manufacturer

Art. no.: 0-48-0060 Rev.: a

10.3.7 Hardware Number

Menu	Parameter	Value
Hardware Nb	**Hardware Nb**	Can only be changed by the manufacturer

10.4 Working Hour Meter

Menu	Parameter	Value
	Runtime	Days/hours/minutes
	Standby	Days/hours/minutes
	Lower battery	Capacity in %
	Upper battery	Capacity in %

The working hour meter can only be reset by the manufacturer.

10.5 Ethernet

Menu	Parameter	Value
[Ether]	Mac address	Can only be changed by the manufacturer
	Ip address	User Defined
	Subnet mask	User defined
	Gateway	User defined

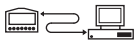
10.6 Options

Menu	Parameter	Value
Options	SpO2	Yes/no
	Non Invasive Blood Pressure	Yes/no
	Printer	Yes/no
	Semiautomatic mode	Yes/no
	Pacemaker	Yes/no
	ECG memory	Yes/no

Art. no.: 0-48-0060 Rev.: a

10.7 Releases

Menu	Parameter	Value
Releases	Group	Soft xy
	FPGA	xy
	Host	xy
	Analog	xy
	Pacemaker	xyxy
	SPO2	xy
	NIBP	xy
	ECG	xy
	VF / VT	xy
	Power	xy
	Defibrillator	xy

10.8 PC Download 

This function is only used for software downloads. To leave the menu, press the "Delete" key twice.

10.9 Locking the Device 

Transport Lock

A locked device will switch off automatically if it is not operated for 5 seconds.

To unlock the device, follow the instructions on the screen.

This menu can only be accessed with the factory password.

Art. no.: 0-48-0060 Rev.: a

11 Maintenance

11.1 Maintenance Interval

Note

The unit must be serviced on a regular basis. The test results must be recorded and compared to the values in the accompanying documents.
The following table indicates the intervals and responsibilities of the maintenance work required.

Interval	Maintenance	Responsible
Before each use	• Visual inspection of the device and electrodes	➜ User
Monthly	• Visual inspection of the device and electrodes • Check of the electrodes' expiration date	➜ User
Every 4 months	• Function inspections according to the instructions	➜ User
Every 12 months	• All measurement inspections and calibration according to the instructions in the service handbook	➜ Service staff authorised by SCHILLER AG
Every 5 years	• Battery replacement	➜ User

11.1.1 Visual Unit Check

Inspect the device and electrodes for the following:
➜ Device casing not deformed?
➜ Electrode connection undamaged?
➜ Expiration date on the electrode package
Defective units or damaged cables must be replaced immediately.

11.1.2 Defibrillator Test

This test can only be carried out with paddles.

⚠ DANGER

▲ Danger of electrical shock. The metal parts of the paddles must not be touched while a shock is triggered.
▲ To prevent the bleeder resistor from overheating, this test must never be carried out several times in a series.

1. Connect the paddles and set the energy to 90 joules.
2. Hold the paddles together and trigger a shock into the device.
3. Recorder printout with the message: **DEFIBRILLATOR TEST – Date – OK**.

Art. no.: 0-48-0060 Rev.: a

11.1.3 Functional Test

➜ Switch the device on and carry out a self-test.

11.1.4 Alarm Tests

Heart rate

1. Start the ECG monitoring (see section 4.3.4, page 28).
2. Set the high and then the low heart rate threshold below/above the measured values.
3. An alarm is issued.

Reset the alarm limits to their original values.

SpO2

See section 4.4, page 30.

NIBP

1. Start the NIBP monitoring (see section 4.5.1, page 33).
2. Set the NIBP alarm limits below/above the measured values and take a new measurement.
3. When the measured value exceeds the alarm limit, an alarm is issued.
4. Reset the alarm limits to their original values.

If the device does not behave as described in this user guide, there is an error that must be repaired by the after-sales service.

Art. no.: 0-48-0060 Rev.: a

11.2 Maintenance Interval for the Battery

Important

The battery is maintenance free during its normal life.
The battery must be replaced after five years, regardless of whether the device has been used or not.

11.2.1 Battery Disposal

WARNING

- ▲ Danger of explosion! Battery may not be burned or disposed of domestic refuse.
- ▲ Danger of acid burns! Do not open or heat up the battery.

The battery is to be disposed of in municipally approved areas or sent back to SCHILLER AG.

11.2.2 Disposal at the End of the Device's Useful Life

The device must be disposed of in a municipally approved collection point or recycling centre.

If there is no local collection point or recycling centre in your area, you can return the device to the distributor or the manufacturer for proper disposal. In this way, you contribute to the recycling and other forms of utilisation of old electrical and electronic equipment.

Improper disposal harms the environment and human health due to dangerous substances contained in electrical and electronic equipment.

Art. no.: 0-48-0060 Rev.: a

11.3 Cleaning

11.3.1 Cleaning the Casing

⚠WARNING

- ▲ Switch the unit off before cleaning and remove the battery. Do not, under any circumstances, immerse the apparatus into a cleaning liquid or sterilise with hot water, steam, or air.
- ▲ Do not use any phenol-based agents or peroxide compounds for cleaning.

- ➜ Wipe the unit's casing with a tissue dampened in a cleaning or disinfection solution (70% alcohol). Make sure that no liquid enters the unit.
- ➜ Discard the disposable pads immediately after use to prevent their reuse (hospital waste).
- ➜ The paddles and their leads can be cleaned and disinfected by wiping them down with a gaze pad moistened with soap water or disinfectant. Before using the paddles again, however, make sure that they are not completely dry.
- ➜ The spoon electrodes can be cleaned in the same way. Further more, these electrodes and the connection cables can be sterilised with ethylene oxide, vapour (134 °C) or ionising radiation. Ensure that internal defibrillation electrodes are sterilised before each use!
- ➜ Before cleaning the electrode or sensor leads, disconnect them from the device. The lines can be cleaned and disinfected by wiping them down with a gaze pad moistened with cleaning agent or disinfectant. Do not immerse the cable connectors in liquid. The device can be cleaned with all cleaning agents and disinfectants commonly used in hospitals.

11.3.2 Accessories and Disposables

⚠WARNING

- ▲ Always use SCHILLER replacement parts and disposables, or products approved by SCHILLER. Failure to do so may endanger life and invalidate the guarantee.

Your local representative stocks all the disposables and accessories for the DEFIGARD® 5000. A full list of all SCHILLER representatives can be found on the SCHILLER website (www.schiller.ch). In case of difficulty, contact our head office in Switzerland. Our staff will be pleased to help process your order or to provide any details for all SCHILLER products.

Art. no.: 0-48-0060 Rev.: a

11.4 Error Detection

11.4.1 General Errors

Error	Cause	Remedy
The screen is not lit when the device is switched on	• Battery not correctly inserted or defective	➜ Correctly insert or replace the battery
	• Device defective	➜ Replace the device
The device cannot be switched off	• Green button was pressed for less than 3 seconds	➜ Keep the green button pressed for at least 3 seconds
	• Device defective	➜ Replace the device
No analysis	• ECG signal too weak	➜ Resume the heart massage
	• ECG signal disturbed by electro-magnetic waves	➜ Switch off the interfering device, e.g. wireless equipment or handy, or move the patient out of the noise field
	• Patient moved or touched during the analysis	➜ The patient must not move or be touched during the analysis
	• Device defective	➜ Replace the device
No shock can be delivered	• Battery charge too low	➜ Change batteries
	• Electrode defect caused by re-suscitation measures	➜ Reapply electrodes
	• Heart rate has changed	➜ Repeat the analysis
	• Device defective	➜ Replace the device

Art. no.: 0-48-0060 Rev.: a

11.4.2 Technical Error Messages

Alarm				
CARD ERROR!	•	Technical error	→	Replace the device
ANALOG BOARD!	•	Technical error	→	Replace the device
POWER CARD ERROR!	•	Technical error	→	Replace the device
Trend Error	•	Technical error	→	Replace the device
PROCESSOR ERROR	•	Technical error	→	Replace the device
PROGRAM ERROR	•	Technical error	→	Replace the device
ERROR DETECTION CIRCUIT FAILED	•	Technical error	→	Replace the device
SELECTED ENERGY VOLTAGE REFERENCE FAILED	•	Technical error	→	Replace the device
ANALOG/DIGITAL CONVERTER ERROR	•	Technical error	→	Replace the device
CHARGE TRANSISTOR ERROR	•	Technical error	→	Replace the device
SAFETY DISCHARGE CIRCUIT FAILED	•	Technical error	→	Replace the device
COMPENSATION EPROM FAILED	•	Technical error	→	Replace the device
SHOCK BUTTON FAILED	•	Technical error	→	Replace the device
DEFI TIME OUT	•	Technical error	→	Replace the device
CHARGE CIRCUIT FAILED	•	Technical error	→	Replace the device
IGBT ERROR	•	Technical error	→	Replace the device
PIC POWER SUPPLY FAILED	•	Technical error	→	Replace the device
NO COMPATIBILITY BETWEEN HARDWARE AND SOFTWARE	•	Technical error	→	Replace the device

Art. no.: 0-48-0060 Rev.: a

12 Technical Data

Where nothing else is indicated, the data refer to a temperature of 25 °C.

12.1 System Data

Manufacturer	SCHILLER MEDICAL
Device name	DEFIGARD® 5000
Dimensions	289 x 271 x 177 mm (h x l x w)
Weight	5.3 kg
Protection case	IPX 1 (drip-proof)
Power Supply	
Voltage	100 - 240 VAC 50/60 Hz
Power consumption	120 VA
Battery operation	Up to 2 hours; up to 4 hours with additional battery
Fuses	2 x 200 mA (T) at 250 VAC, 2 x 315 mA (T) at 115 VAC
External power supply	11.5 - 48 VDC max., 2.5 A
	The unit is suitable for use in networks according to IEC 60601-1-2.
Battery	
Battery type	Lithium/ion 10.8 V, 4.3 Ah
Autonomy	190 shocks with maximum energy or 2 hour monitoring (with one battery)
Environmental conditions	
For operation	• 0 ºC...40 ºC relative humidity at 30...95% (noncondensing) • Atmospheric pressure 500...1060 hPa
For storage and transport	• -10 ºC...50 ºC relative humidity at 0...95% (noncondensing) • Atmospheric pressure 700...1060 hPa
Display	
Type	High-resolution colour LCD, backlit
Dimensions	211.4 x 158.4 mm (10.4 “)
Printer	High resolution thermo-printer
Resolution	8 dots/mm (amplitude-axis), 40 dots/mm (time-axis) at 25 mm/s
Paper	Thermoreactive, Z-folded, 72 mm width, length approx. 20 m
Print speed	25, 50 mm/s
Recording tracks	3-channel display, with optimal width of 72 mm
Connections	ECG patient cable , SpO_2, NIBP

Art. no.: 0-48-0060 Rev.: a

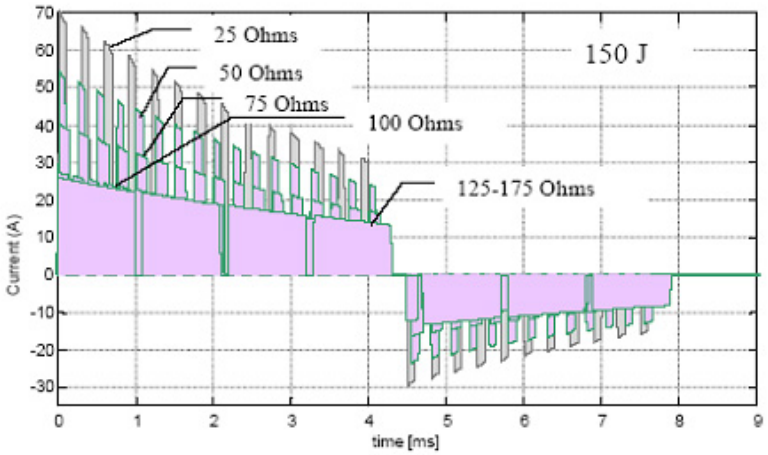
Interfaces	• RS-232 • Analog for QRS trigger, 1-channel ECG and remote alarm (no delay compared to device alarm) • USB • Ethernet • For pins and the signal type, please contact the SCHILLER after-sales service.
Safety standard	IEC/EN 60601-2-4 The device is designed for 2500 shocks
EMC	• IEC/EN 60601-1-2 • IEC/EN 60601-2-4 • CISPR 11 class B The device can be exposed to the following interferences without any impairment: • Static discharge up to 8 kV • Energy in the radio frequency range up to 20 V/m (80...2500 MHz, 5 Hz modulated) • Magnetic fields of 100 A/m, 50 Hz
Conformity	CE according to directive 93/42/EEC class IIb
Safety class	Class I according to IEC/EN 60601-1

Art. no.: 0-48-0060 Rev.: a

12.2 Defibrillation Pulse

Form

- Biphasic pulsed defibrillation impulse with fixed physiological optimum phase durations
- Near stabilisation of the emitted energy in function with the patient resistance using pulse-pause modulation depending on the measured patient resistance.



Standard energy settings

Deviation at 50Ω: ± 3 J oder ± 15 % (the higher value is assumed)

Adult AED
- 130/130/150 joules (configurable)

Paediatric AED
- 15/30/50 joules (configurable)
  (automatic switch when the pediatric electrodes are connected)

Paddle
- 0, 2, 4, 8, 15, 30, 50, 90, 130, 180 joules

Adhesive electrodes
- 2, 4, 8, 15, 30, 50, 70, 90, 110, 130, 150, 180 joules

Internal
- 2, 4, 6, 8, 15, 30 joules

Charging time for shock

(Time used to charge the storage capacitor to the max. energy of 180 J in manual mode)

• with full battery	8 seconds
• with 90 V mains voltage after 15 discharges with max. energy emission	9 seconds
• from switch-on of the device with paddles	18 seconds
• from switch-on of the device with pads	25 seconds

Cycle Time Rhythm Analysis – Shock Standby in AED Mode

• with full battery	1st shock = 20 s; 2nd shock = 40 s; 3rd shock = 60 s
• with 90 V mains voltage after 15 discharges with max. energy emission	1st shock = 20 s; 2nd shock = 40 s; 3rd shock = 60 s
• from switch-on of the device to charge at max. energy	1st shock = 35 s; 2nd shock = 55 s; 3rd shock = 75 s

Cycle time shock - shock

<25 s

Art. no.: 0-48-0060 Rev.: a

Operating Modes	Synchronised with heart action 25 ms after R wave Unsynchronised AED
Charge control and monitoring	• Automatic shock recommendation of analysis in AED mode • Using the set wheel on the paddle • Using the device's keyboard Display of selected energy
Patient resistance	30...220 Ω
Display of shock standby	Key  is lit
Shock delivery	Using key 
Safety discharge when:	• the battery voltage is insufficient • the device is defective • the device is turned off
Shock delivery	• Via applied disposable adhesive defibrillation electrodes • Via paddles • Via spoons
Defibrillation electrode connection	
External defibrillation	BF type
Internal defibrillation	Type CF
Defibrillation electrodes	Electrode cable 1.95 m long
Adult electrode	• 78 cm^2 active surface
Pediatric electrode	• 28 cm^2 active surface
VF/VT detection	**Conditions for ECG analysis** VF/VT detection is only based on the ECG signal. Minimum amplitude for analysable signals > 0.15 mV; signals < 0.15 mV are assessed as asystole **Shock recommendation** In case of VF and VT (VT > 180 p/min) **Sensitivity 96.4 %** Correct detection of shockable rhythms **Specificity 99.8 %** Correct detection of **non**-shockable rhythms These values were determined with an AHA database containing VF and VT with or without artefacts.

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Art. no.: 0-48-0060 Rev.: a

12.3 Technical Data - Measured Values

12.3.1 ECG

Leads	Simultaneous, synchronous recording of all 9 active electrodes giving 12 leads
Patient cable	3-,4-, 10-lead cable, type CF
Heart rate	
Range	• 30 – 300 beats/min
Accuracy	• ±2 beats/min
Lead display	Selection of 1 or 12 simultaneous leads
Sensitivity	0.25, 0.5, 1, 2 cm/mV programmable
ECG amplifier	
Band pass	0.5...35 Hz or 0.05...150 Hz (depending on the ECG source)
Blockage caused by defibrillation shock	Max. 5 seconds

12.3.2 NIBP - Non-Invasive Blood Pressure

Measurement	Automatic or manual
Measuring method	Oscillometric
Connection	Type CF
Measurement range	
Adults	• Sys 30...255 mmHg, dia 15...220 mmHg
Neonates	• Sys 30...135 mmHg, dia 15...110 mmHg
Accuracy	± 3 mmHg and ± 2 beats/min

Art. no.: 0-48-0060 Rev.: a

12.3.3 SpO_2 - Pulsoximetry

Amplifier	Masimo™
Operation	Normal and sensitive
Accuracy	**SpO_2** • Adults 1 to 100% ± 2 digits • Neonates 70 to 100% ± 3 digits **PP** • 25...240/min ± 4 digits
Calibration range	70...100%
Connection	Type CF
Measurement range	**SpO_2** 1...100% **PP** 25...240/min
Displayed range	1...100%
Blockage caused by defibrillation shock	Max. 10 seconds

12.3.4 Storage of Intervention (Option)

Saving	
ECG	45 minutes
Events	500 pcs.

12.4 Technical Pacemaker Data

Operating Modes	• Demand • Fixed-rate mode • Overdrive (pulse frequency x 3)
Stimulation pulse	
Form	Rectangle
Duration	40 ms (20 ms overdrive mode) ± 10%
Pulse rate	Configurable in steps of 40...210 beats/min, ± 5%
Pulse current	Configurable in the range of 0...150 mA, ± 5%
Signal connection	Type CF, defibrillation protected
Readiness for operation	Immediately

Art. no.: 0-48-0060 Rev.: a

13 Appendix

13.1 Accessories DEFIGARD 5000

Defibrillation accessories

Article no.	Article description
1-101-3002	Adapter module for internal defibrillation
W1410013	Connection cable for spoon electrodes
W1409505	Spoon electrodes, pediatric, oval 43 x 27 mm - 9 cm^2
W1403835	Spoon electrodes, pediatric, round 45 mm - 16 cm^2
W1403834	Spoon electrodes, neonatal, 6 cm^2
6-34-0005	Spoon electrodes, adult (pkg of 2), 54 cm^2
1-101-3000	Paddle cassette
35131	Defibrillation gel (250 ml)
1-101-3001	Adapter module pads
EASY ELEC	Adult pads
0-21-0000	Pediatric pads
0-21-0008	Defibrillation paddle adapter for children (x1)

ECG accessories

Article no.	Article description
W1402037	10-lead patient cable, clip, 45° plug
W1409608	3-lead patient cable, clip, 45° plug
U50063	4-lead patient cable, clip, 45° plug
W1402262	4-lead patient cable, banana plug, 45° plug
72365	ECG electrodes 34 mm, (x50) for clip cable
72366	ECG electrodes with holding strap, 34 mm, (x50) for banana plug cable

SpO2 accessories

Article no.	Article description
2.100408	Disposable sensor for adults LNOP/ADT (x20)
2.100409	Disposable sensor for children LNOP/ADT (x20)
0-05-0003	SPO_2 Masimo extension cable 2.5 m
0-05-0010	SPO_2 Masimo extension cable 5 m
0-05-0011	SPO_2 Masimo extension cable 10 m
2.100303	SPO_2 Masimo finger sensor, adult
2.100305	SPO_2 Masimo finger sensor, pediatric

Art. no.: 0-48-0060 Rev.: a

NIBP accessories

Article no.	Article description
U50128	Adult cuff 14 cm
U50129	Pediatric cuff 7 cm
W1405268	Air hose 1.5 m
0-22-0001	Air hose 3 m

Pacemaker accessories

Article no.	Article description
0-21-0013	Pacemaker/defibrillation pads adult

Various accessories

Article no.	Article description
2.300005	Power cable 2P+T, 2.5 m, 90° plug, European standard
W1403916	Connection cable 12 VDC - 30 V
0-50-0000	Paper
2.200132	Additional rechargeable battery Li/ion 10.8V, 4.3 Ah
U50030	Earth cable

Art. no.: 0-48-0060 Rev.: a

13.2 Literature

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Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Resuscitation 46.

American Heart Association (2000)
Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Suppl. to Circulation Volume 102 – Number 8.
ISBN 0-87 493-325-0.

Cansell A. (2000)
Wirksamkeit und Sicherheit neuer Impulskurvenformen bei transthorakaler Defibrillation - Biphasische Impulskurvenformen - Notfall & Rettungsmedizin,
Springer Verlag 3 : 458 – 474.

13.3 Glossary

ABCD The primary ABCD
A = Airways (check if airways are free)
B = Breathing (artificial respiration)
C = Circulation (circulatory signs or cardiac massage)
D = Defibrillation

ACLS Advanced Cardivascular Life Support. (ACLS Manual AHA 2001)

AED Automatic external defibrillator

BLS Basic Life Support (artificial respiration and cardiac massage)
CPR is frequently used synonymously

CPR Cardiopulmonary resuscitation

PEA Pulseless electrical activity

VT Ventricular tachycardia

VF Ventricular fibrillation

Art. no.: 0-48-0060 Rev.: a

Art. no.: 0-48-0060 Rev.: a

14 Index

Art. no.: 0-48-0060 Rev.: a

Art. no.: 0-48-0060 Rev.: a